



US008938283B2

(12) **United States Patent**
Zentgraf et al.

(10) **Patent No.:** **US 8,938,283 B2**
(45) **Date of Patent:** **Jan. 20, 2015**

- (54) **SURGICAL NAVIGATION FOR REPAIR OF HEART VALVE LEAFLETS**
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- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 54 days.

USPC 600/424; 600/443; 382/131
 (58) **Field of Classification Search**
 USPC 600/424; 382/128, 131, 132
 See application file for complete search history.

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- (21) Appl. No.: **13/692,027**
- (22) Filed: **Dec. 3, 2012**
- (65) **Prior Publication Data**
 US 2013/0150710 A1 Jun. 13, 2013

Related U.S. Application Data

- (60) Provisional application No. 61/565,795, filed on Dec. 1, 2011.

(51) **Int. Cl.**

A61B 8/00 (2006.01)
A61B 8/08 (2006.01)
A61B 8/12 (2006.01)
A61B 17/04 (2006.01)
A61B 19/00 (2006.01)
A61B 17/00 (2006.01)
A61B 17/06 (2006.01)

(52) **U.S. Cl.**

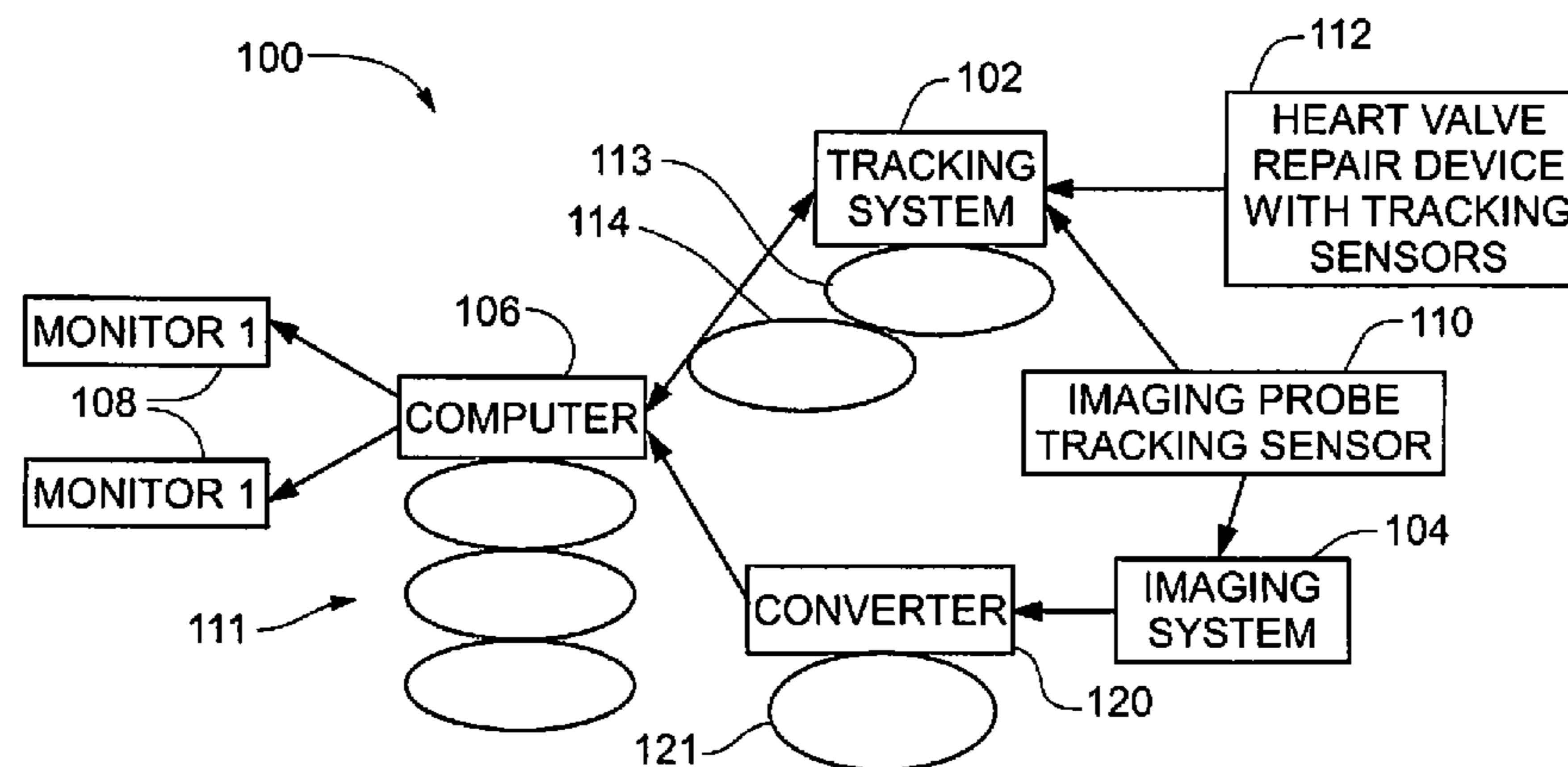
CPC . **A61B 8/461** (2013.01); **A61B 8/58** (2013.01);
A61B 8/0841 (2013.01); **A61B 8/12** (2013.01);
A61B 8/4254 (2013.01); **A61B 17/0469**
 (2013.01); **A61B 19/5244** (2013.01); **A61B**
19/56 (2013.01); **A61B 17/0482** (2013.01);
A61B 2017/00243 (2013.01); **A61B 2017/06042**
 (2013.01); **A61B 2019/507** (2013.01); **A61B**
2019/5251 (2013.01); **A61B 2019/528**
 (2013.01); **A61B 2019/5291** (2013.01)

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(57) **ABSTRACT**

To improve the overall navigation process for minimally invasive repair of heart valve leaflets, an augmented reality technique capable of providing a robust three-dimensional context for transesophageal echocardiography data has been developed. In the context of various embodiment of the invention, augmented reality essentially refers to a system in which the primary environment is virtual but the environment is augmented by real elements. In this real-time environment, the surgeon can easily and intuitively identify the tool, surgical targets, and high risk areas, and view tool trajectories and orientations.

22 Claims, 17 Drawing Sheets



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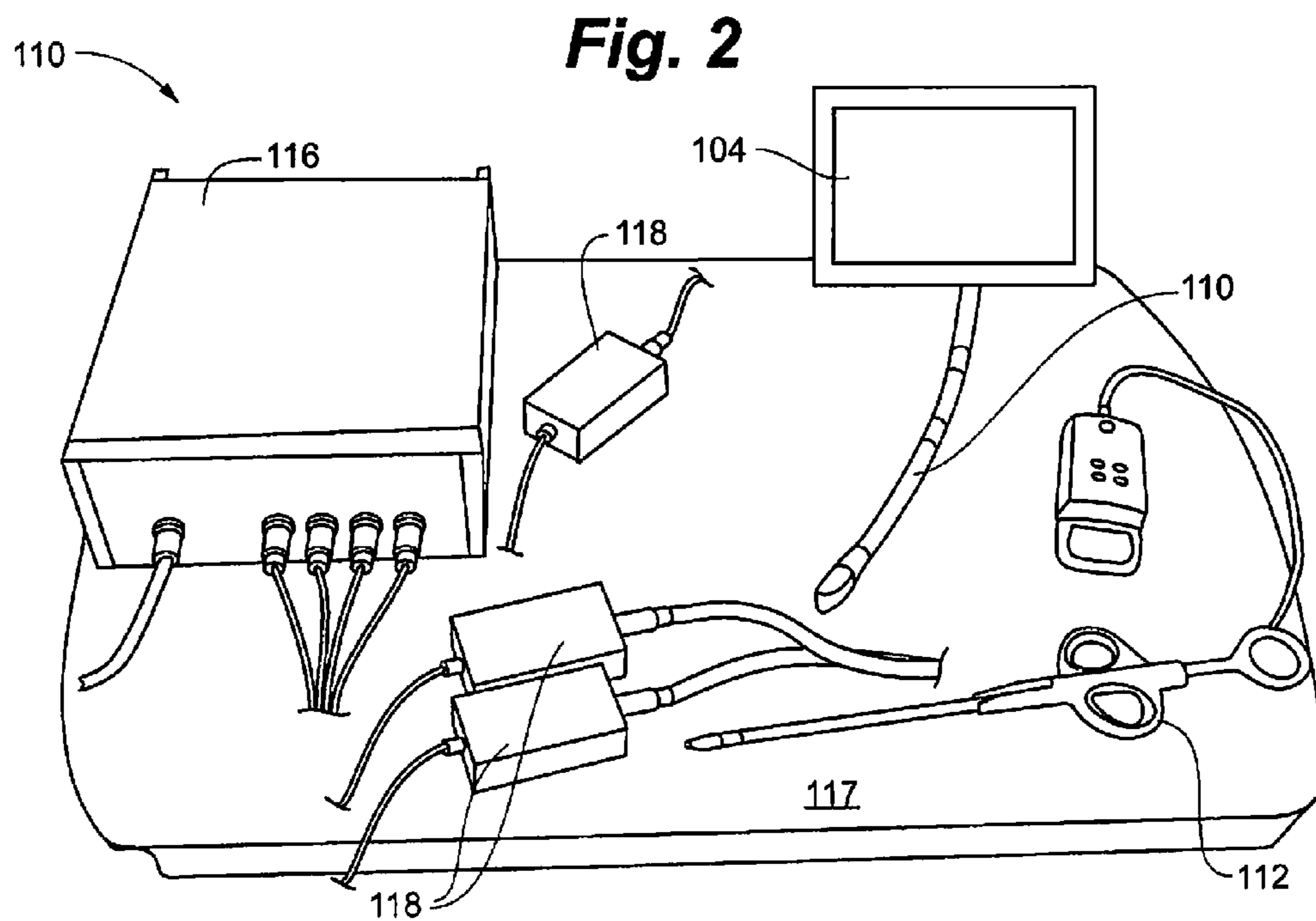
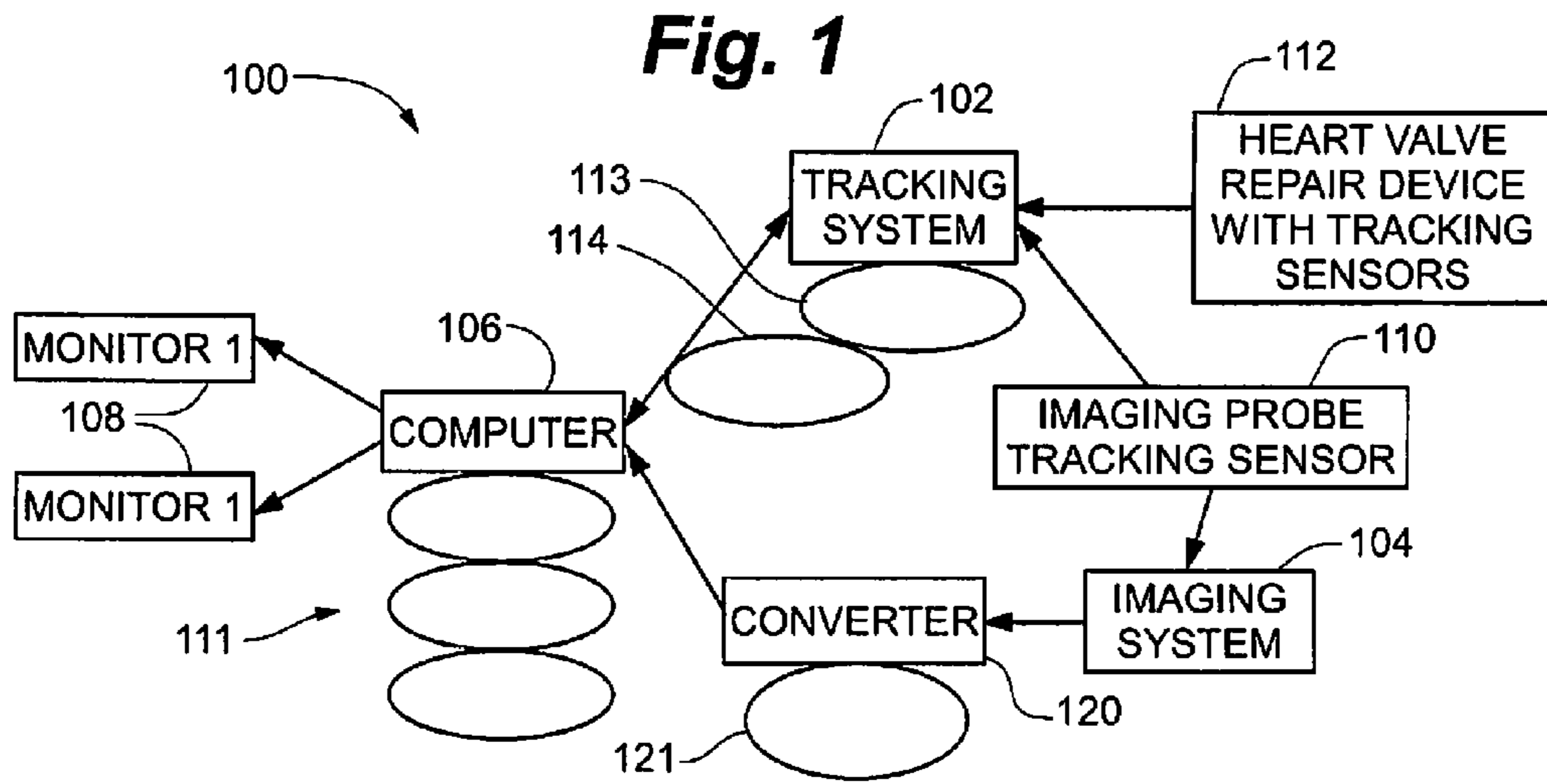


Fig. 3

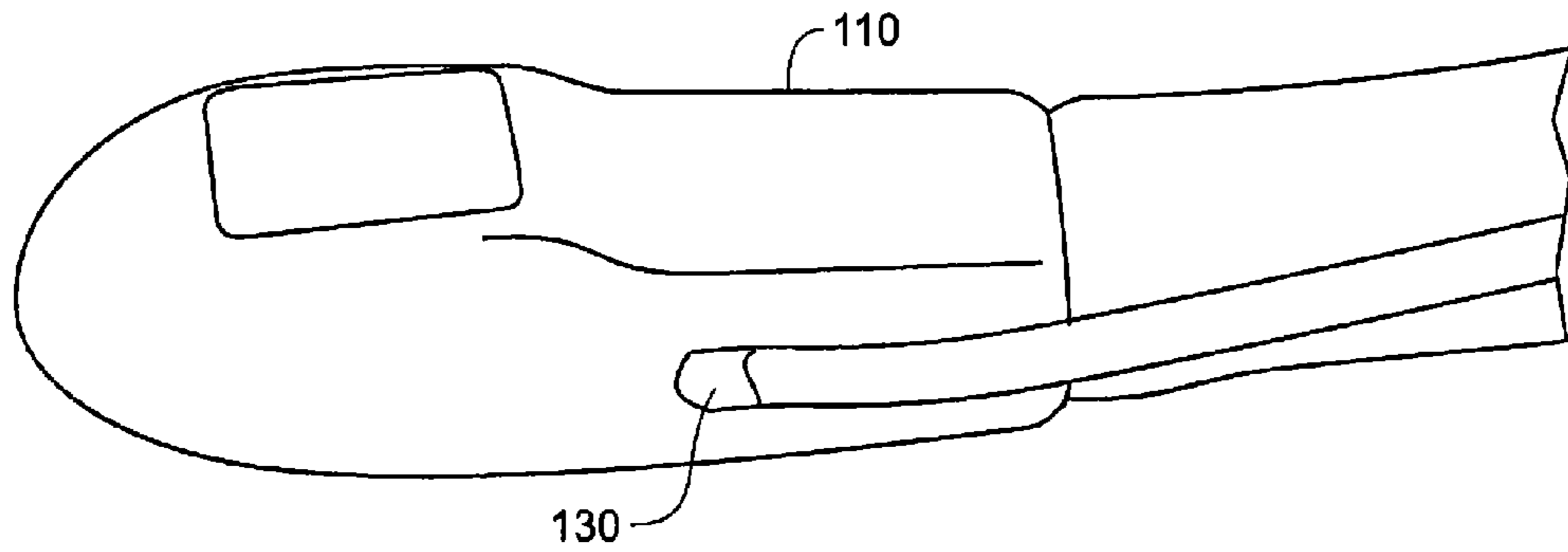


Fig. 10

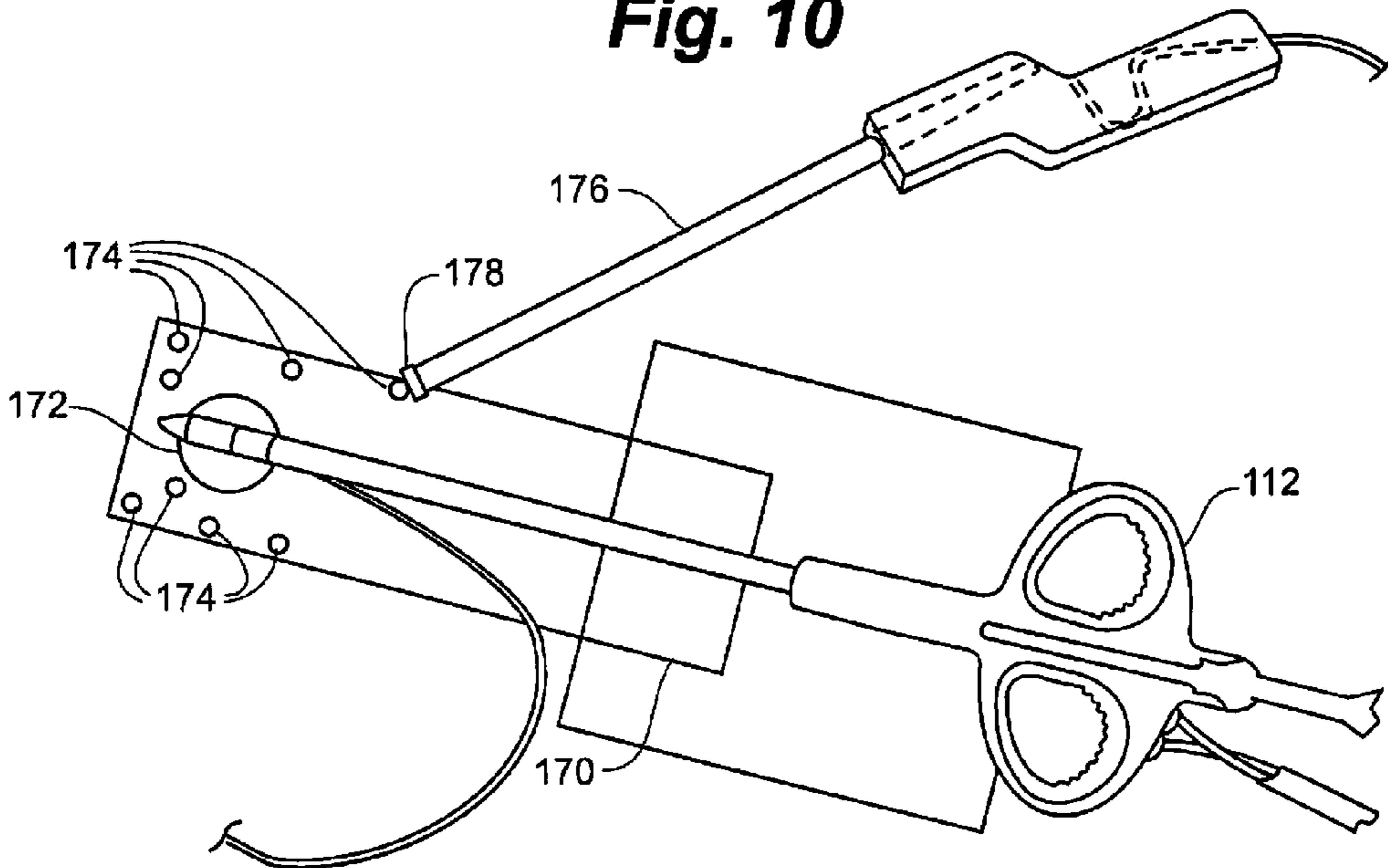


Fig. 4

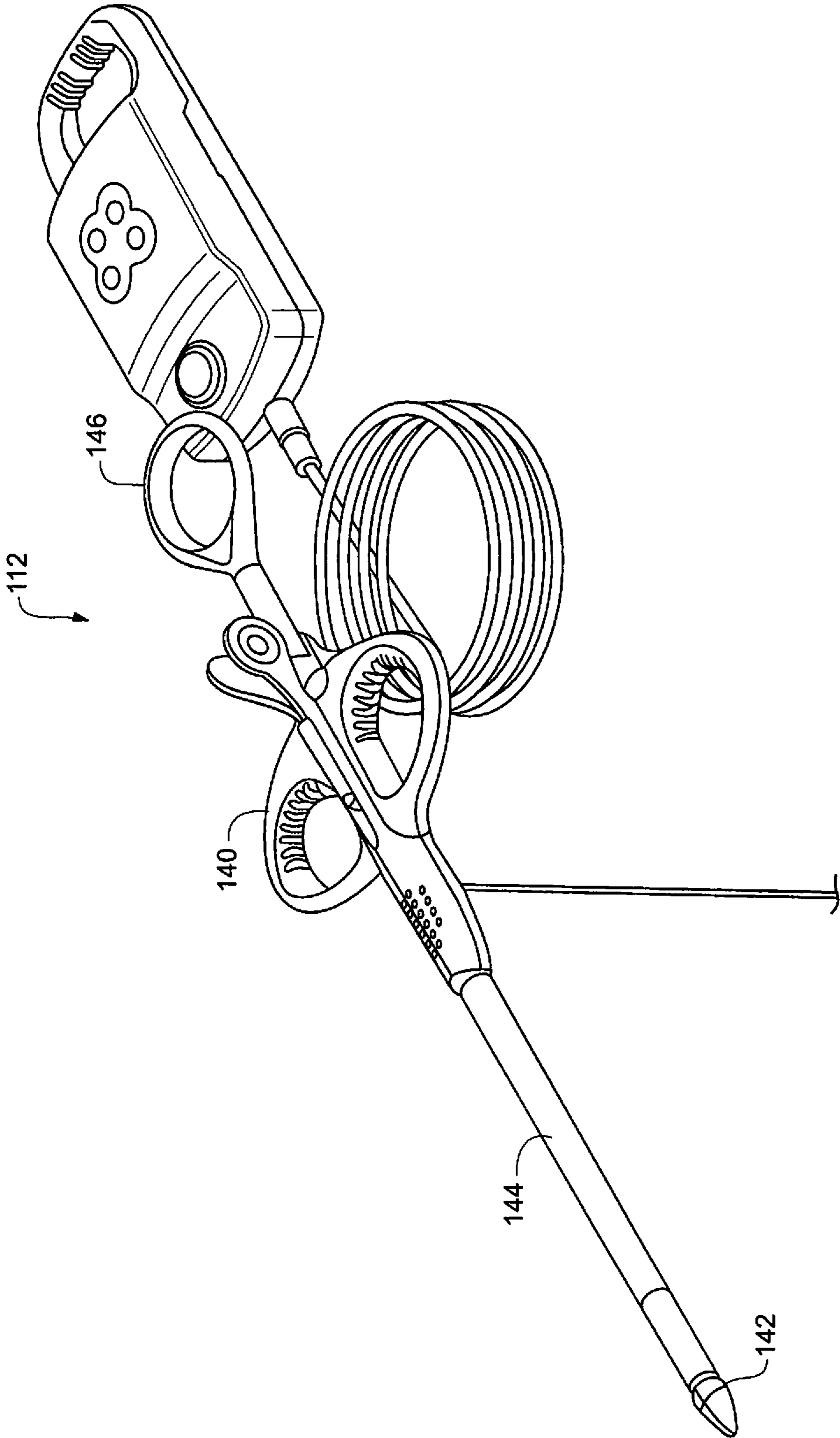


Fig. 5A

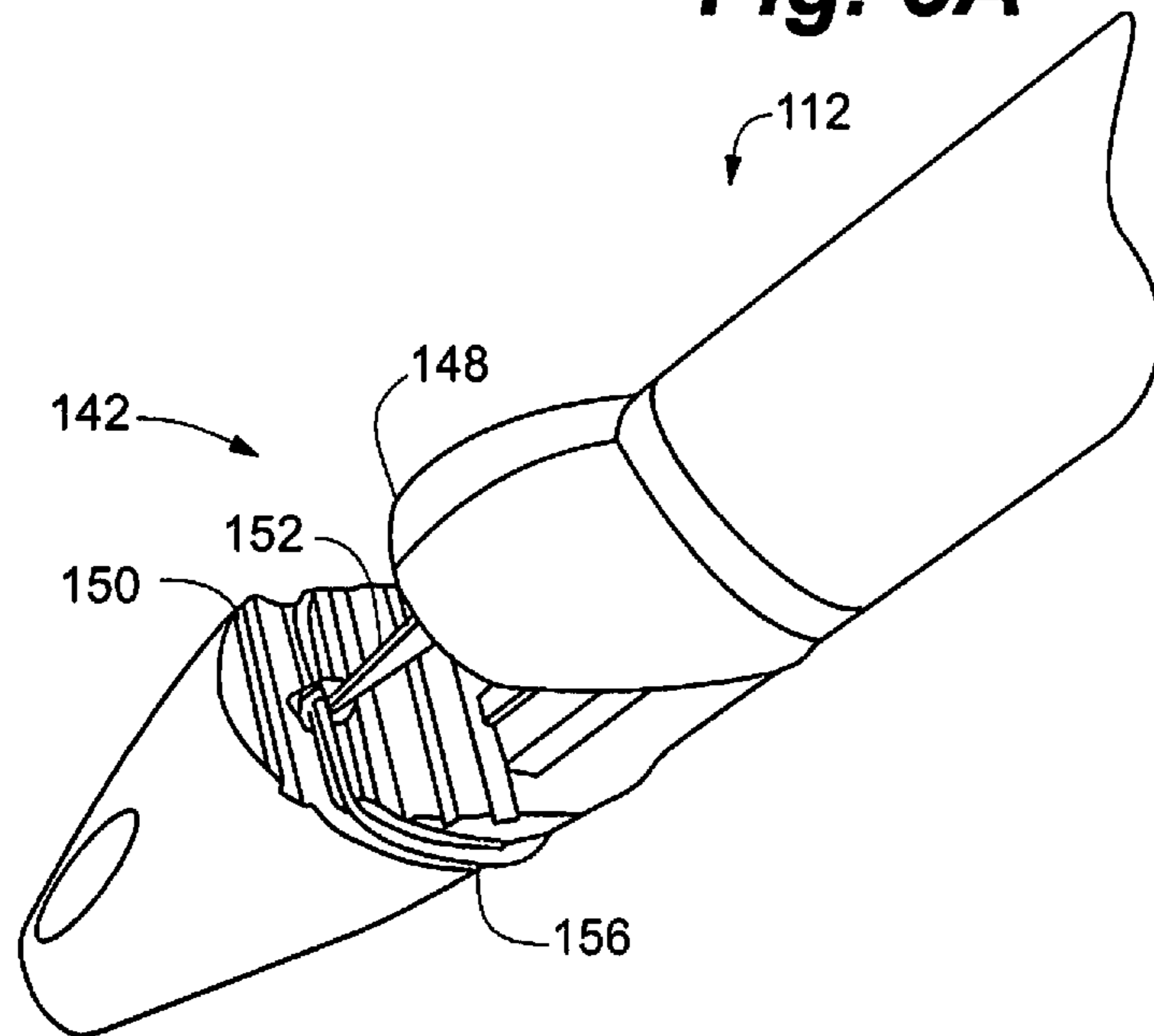


Fig. 5B

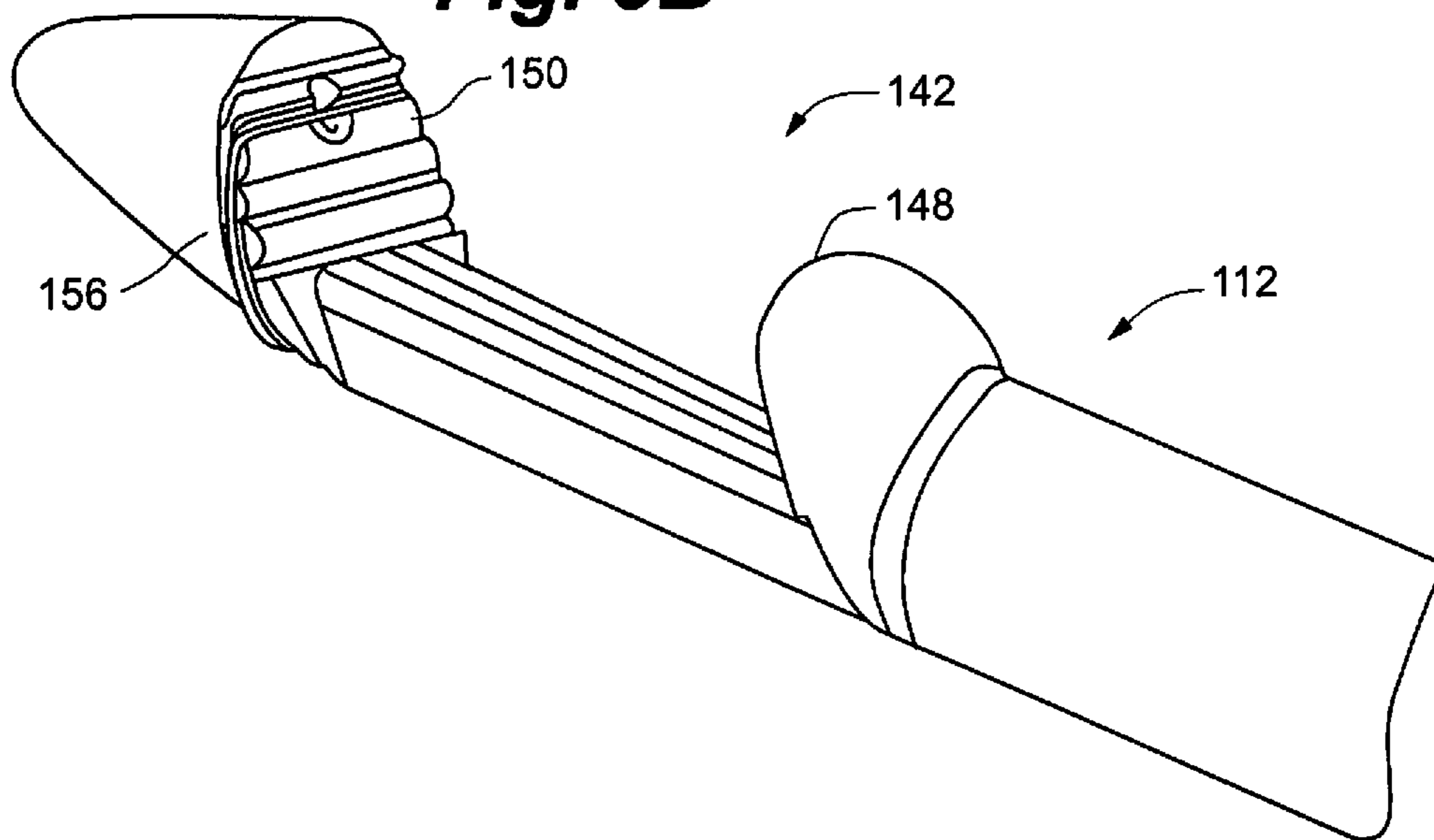


Fig. 6

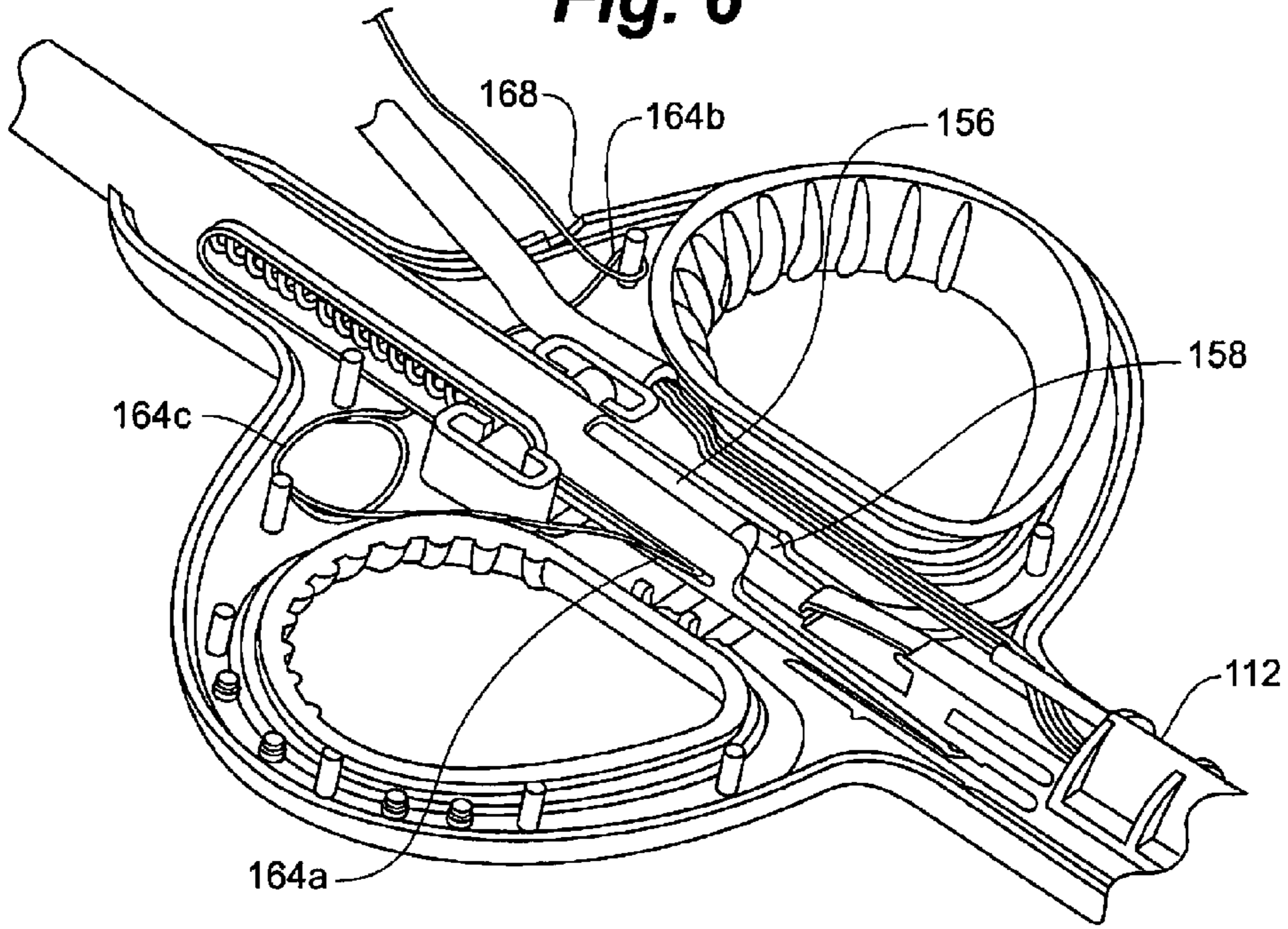


Fig. 7

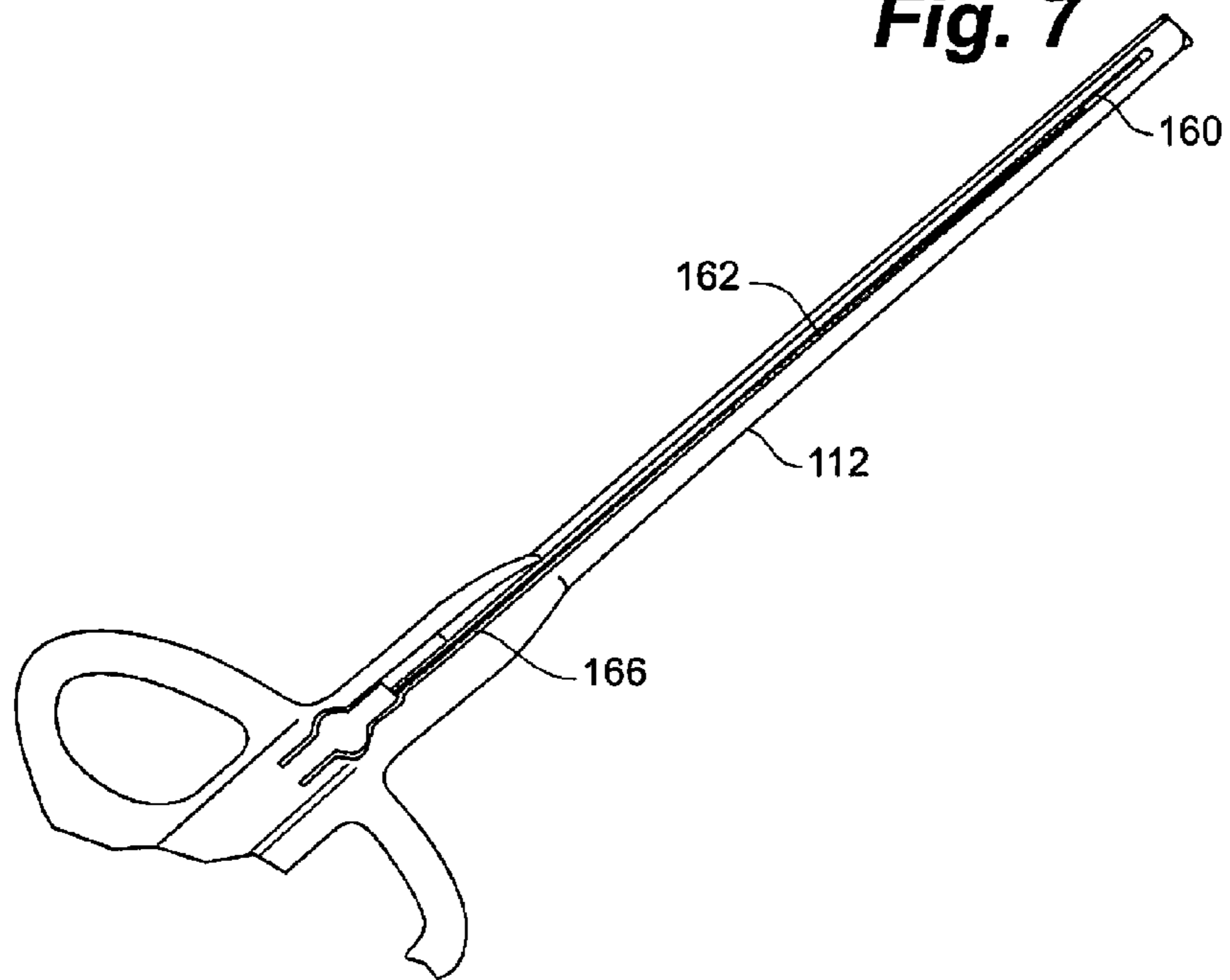


Fig. 8

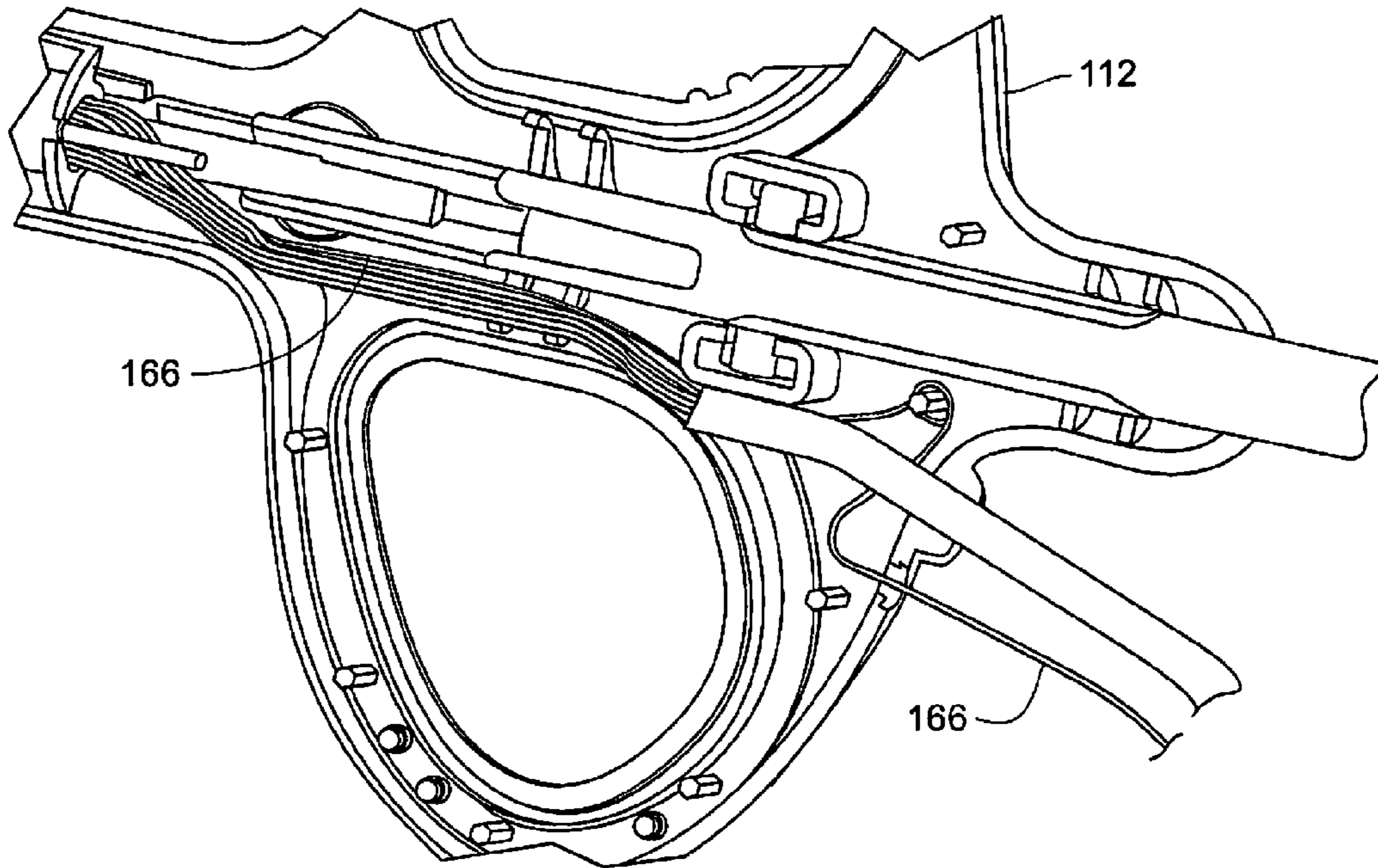
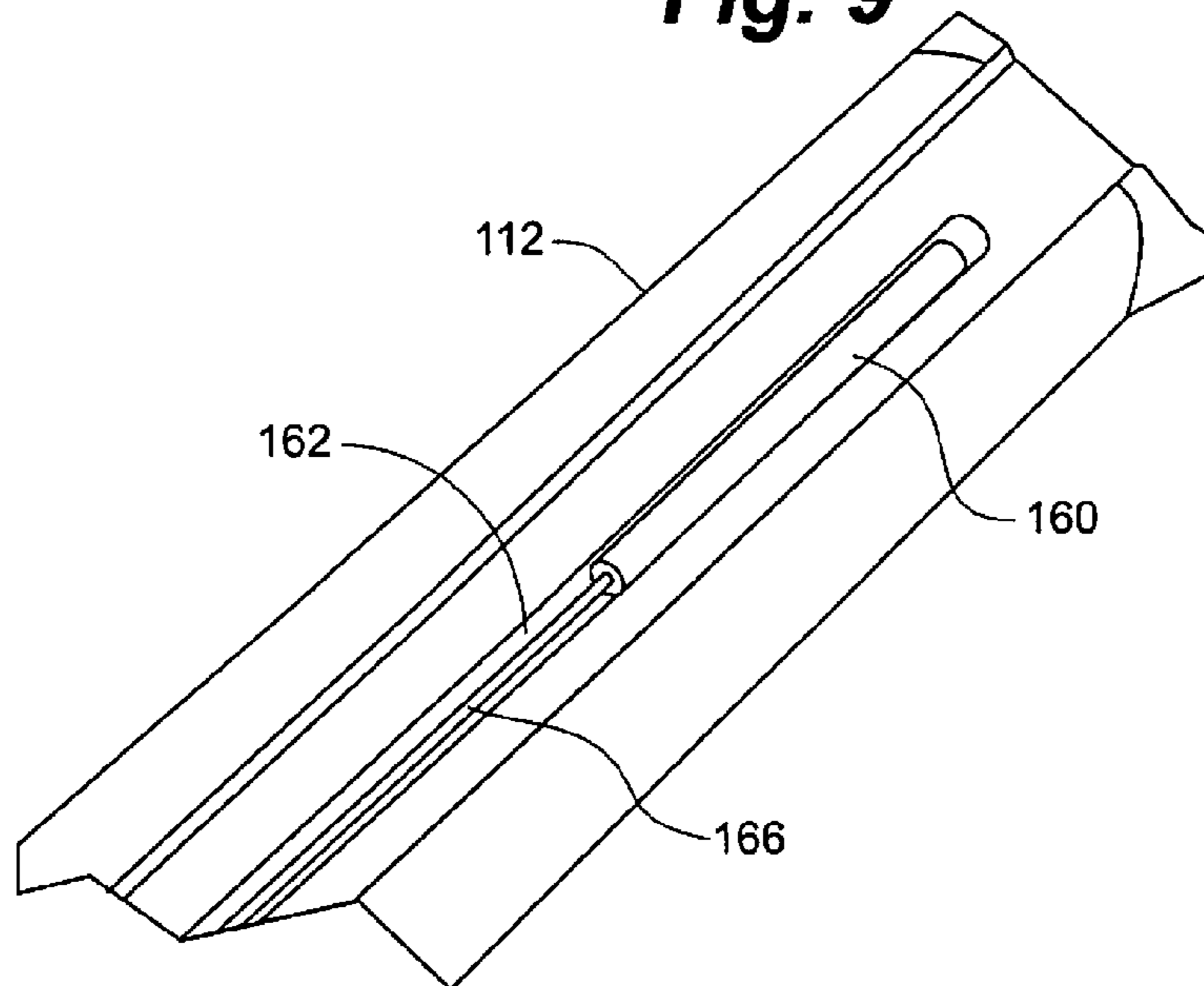


Fig. 9



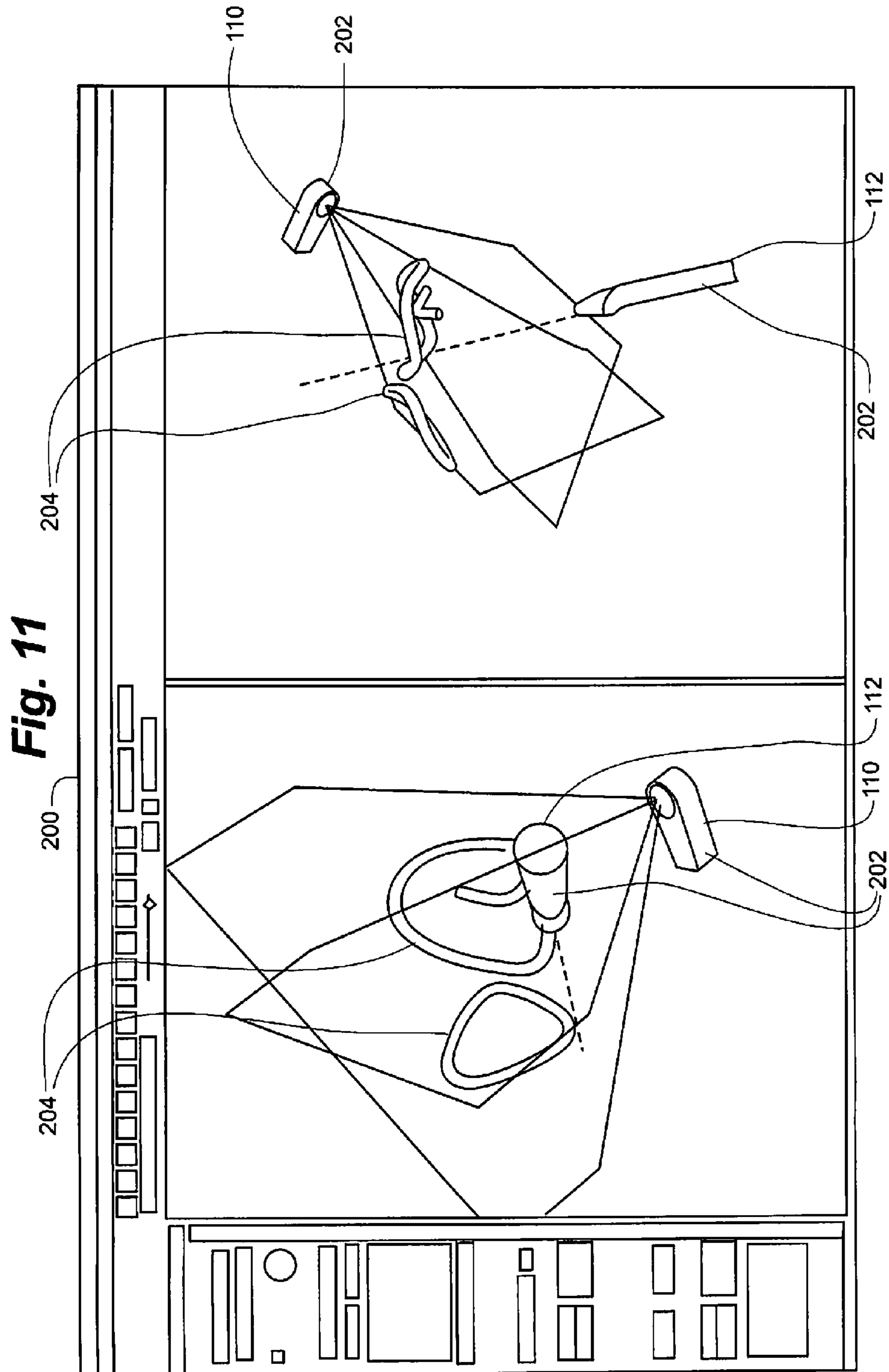
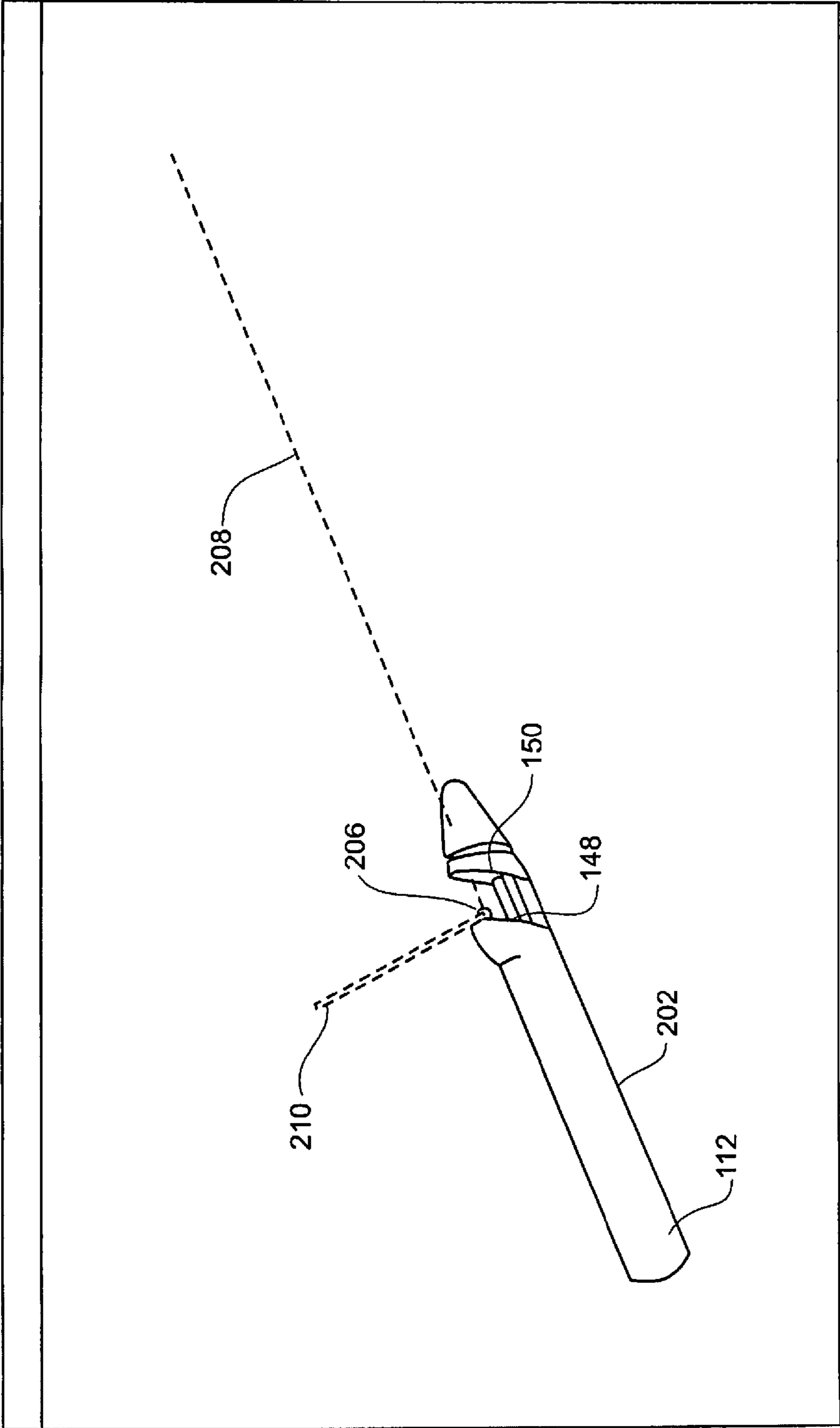


Fig. 12



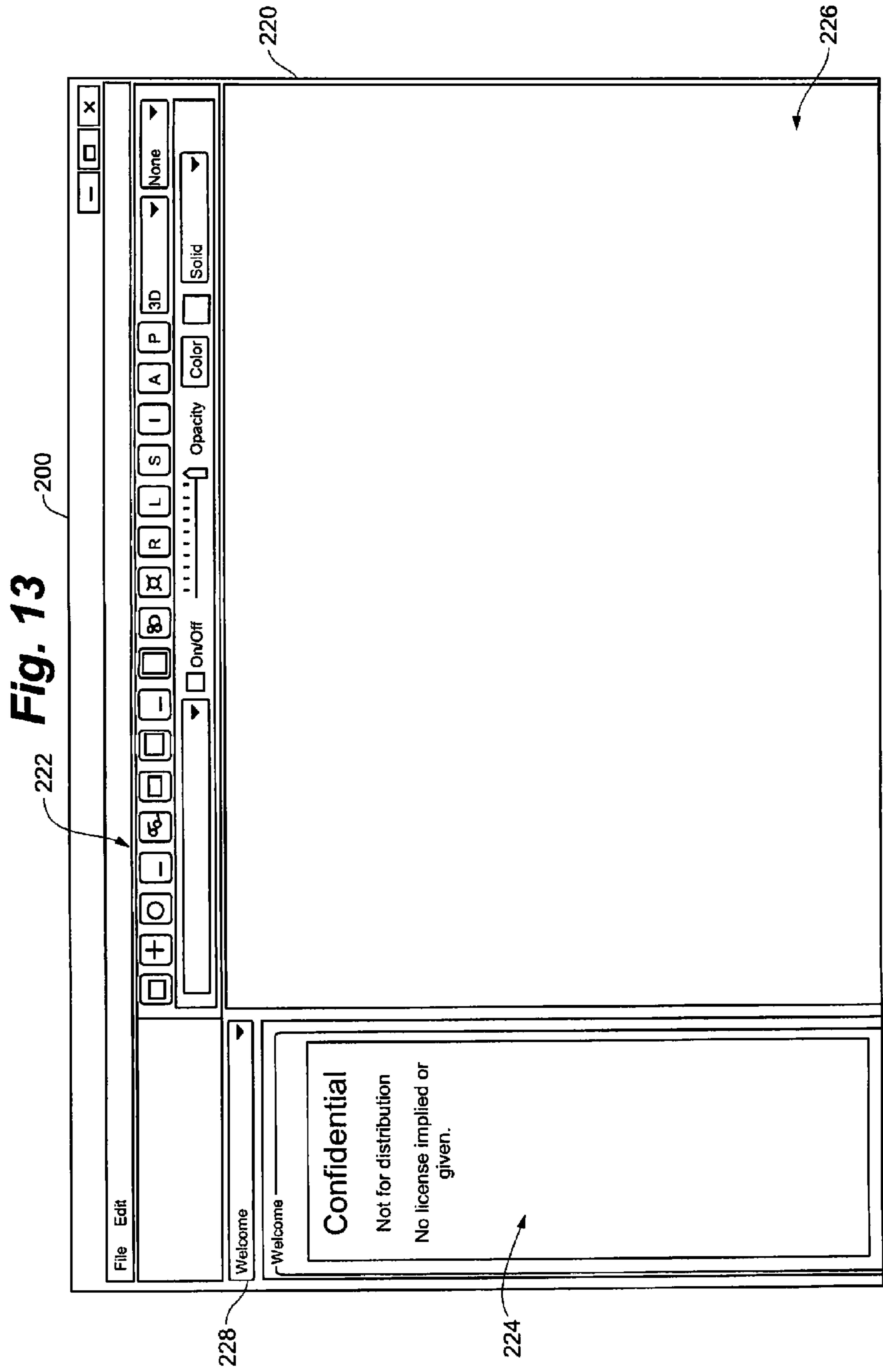


Fig. 14

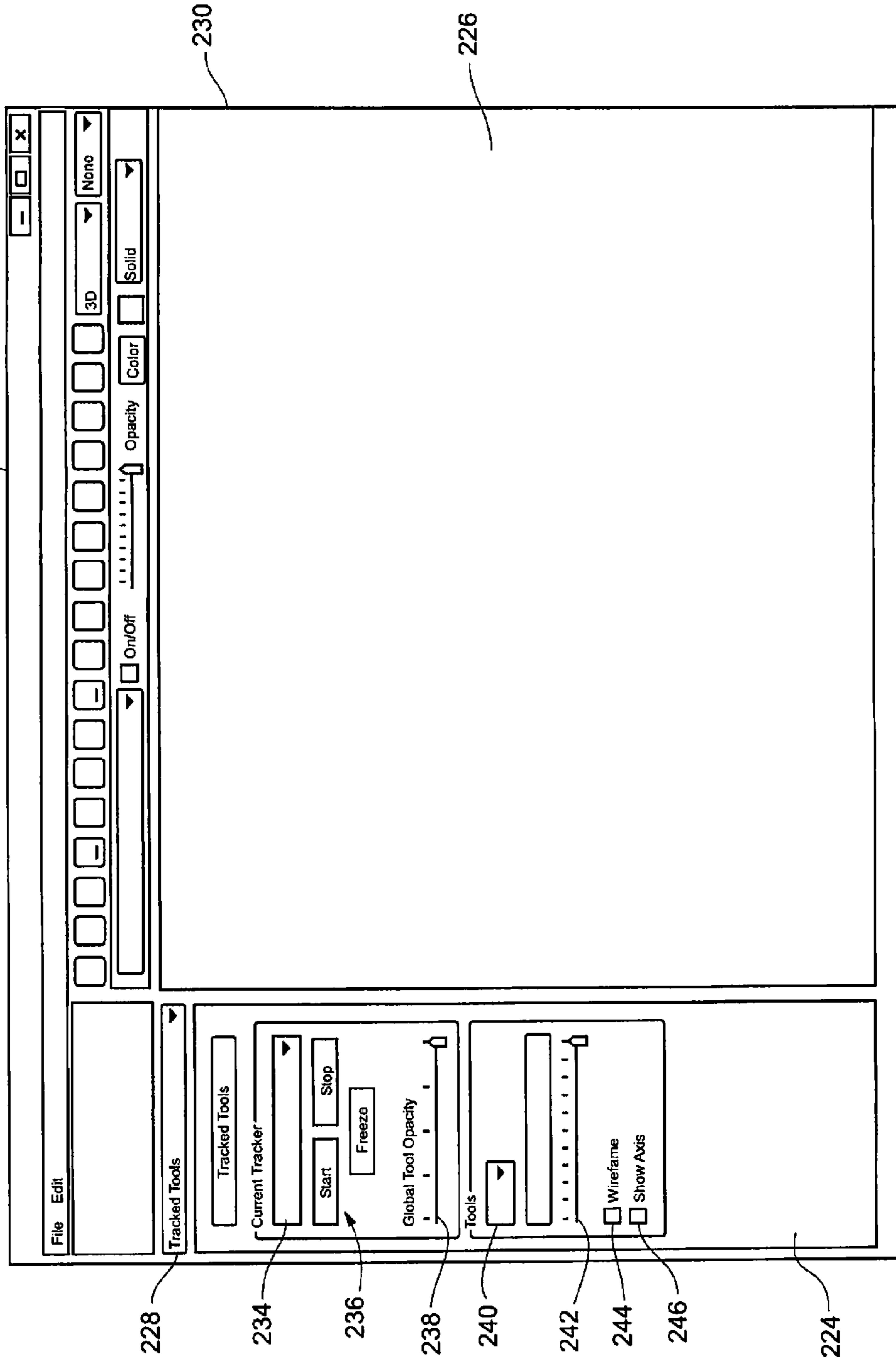


Fig. 15

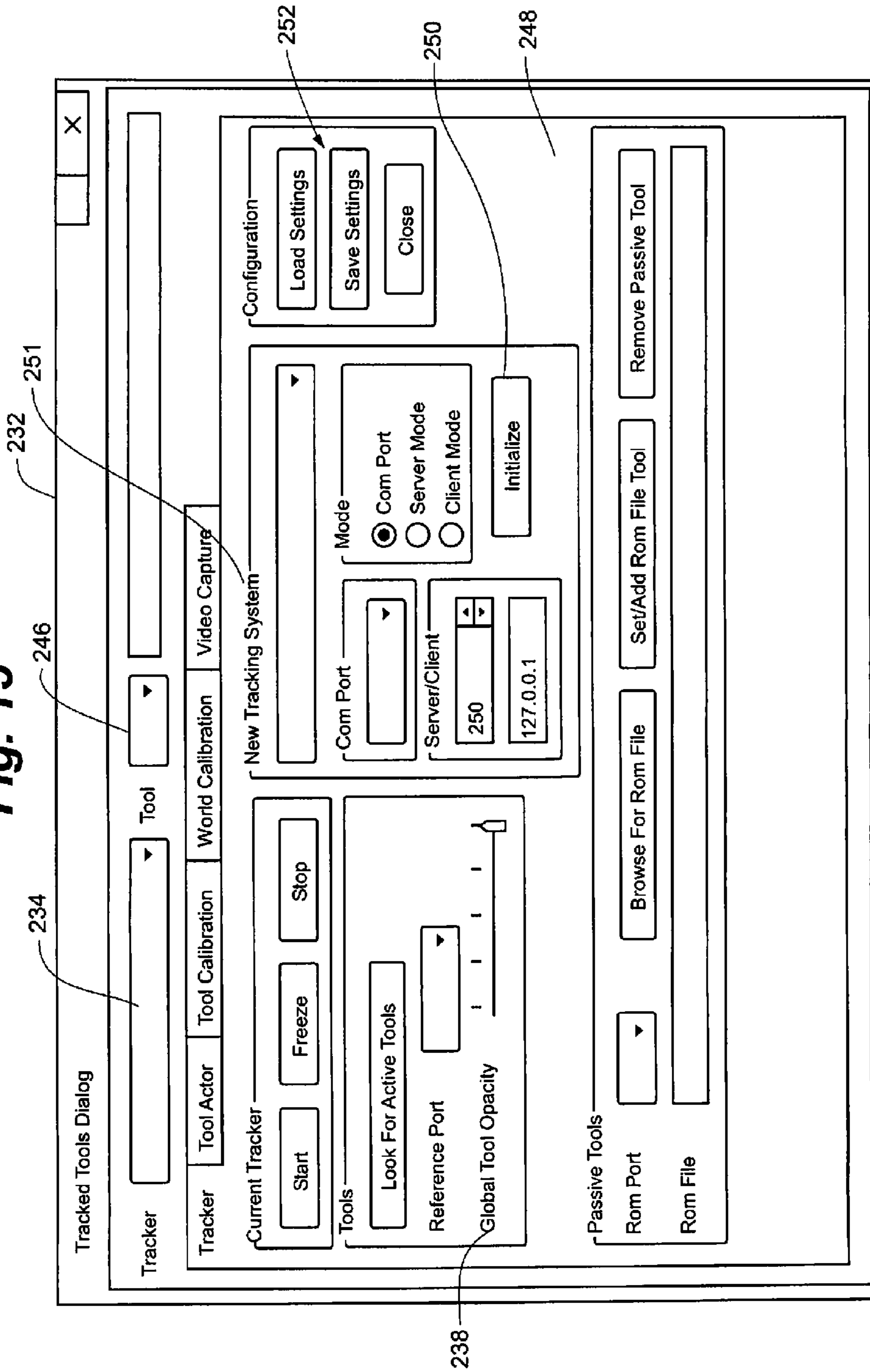


Fig. 16

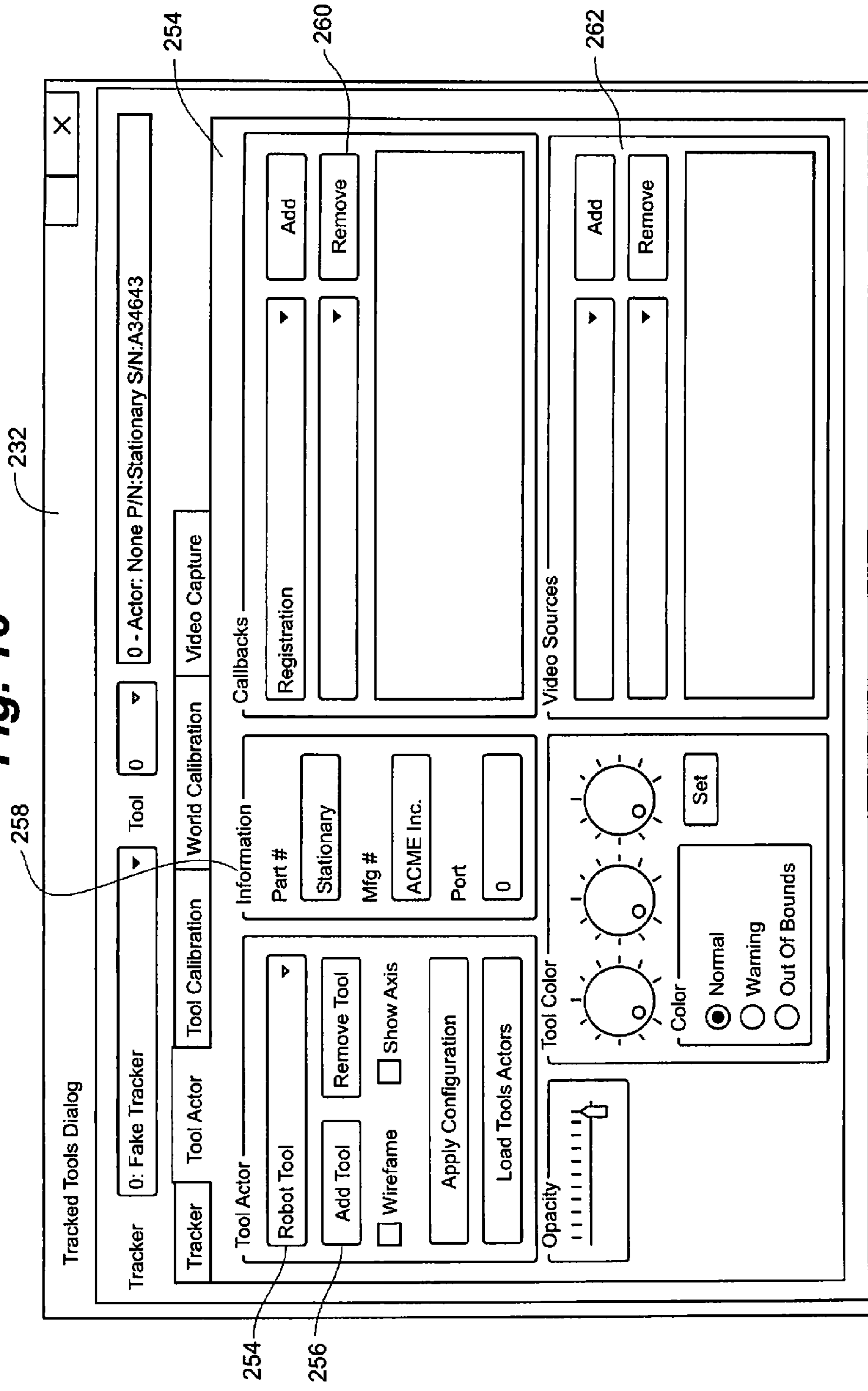


Fig. 17

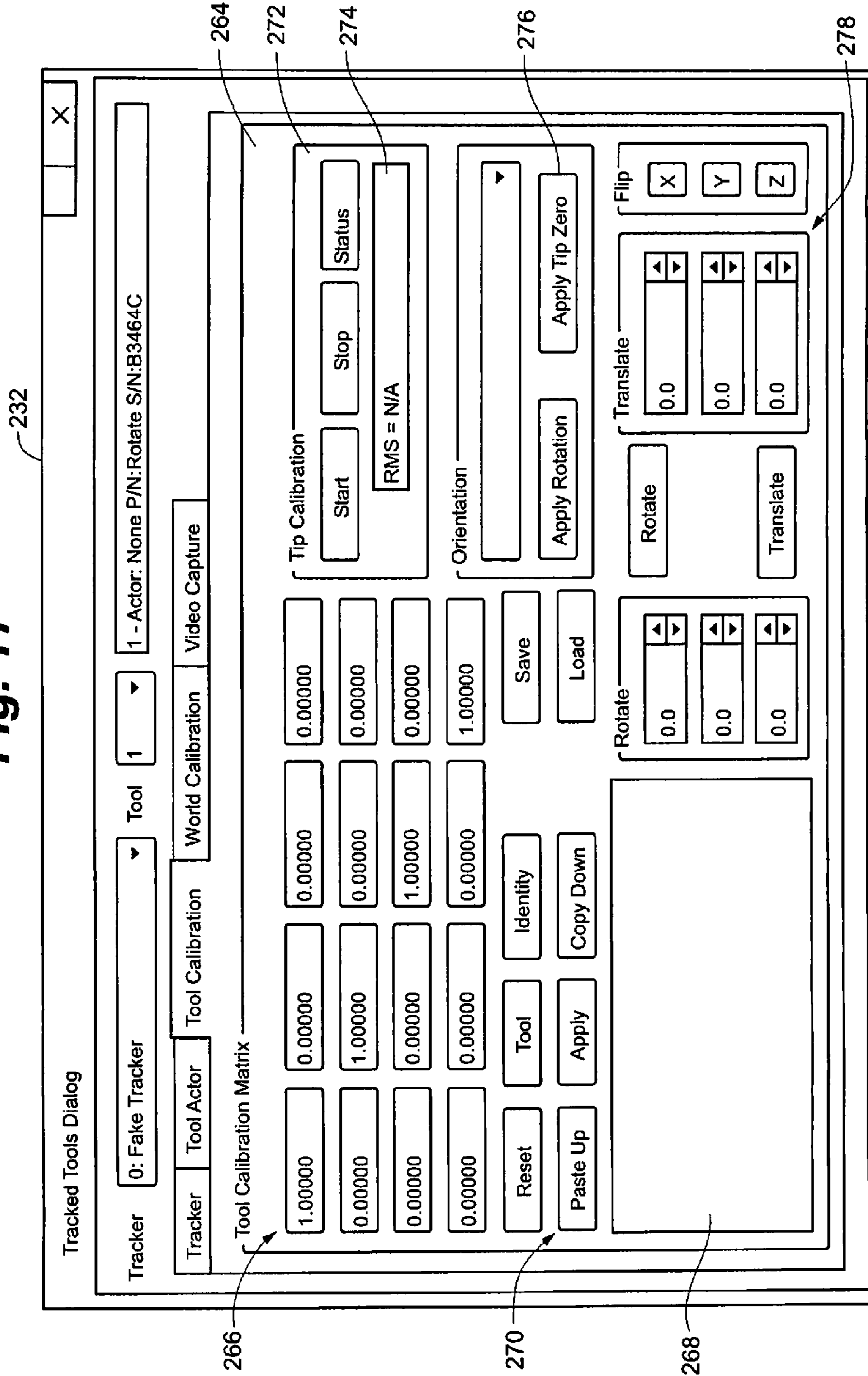
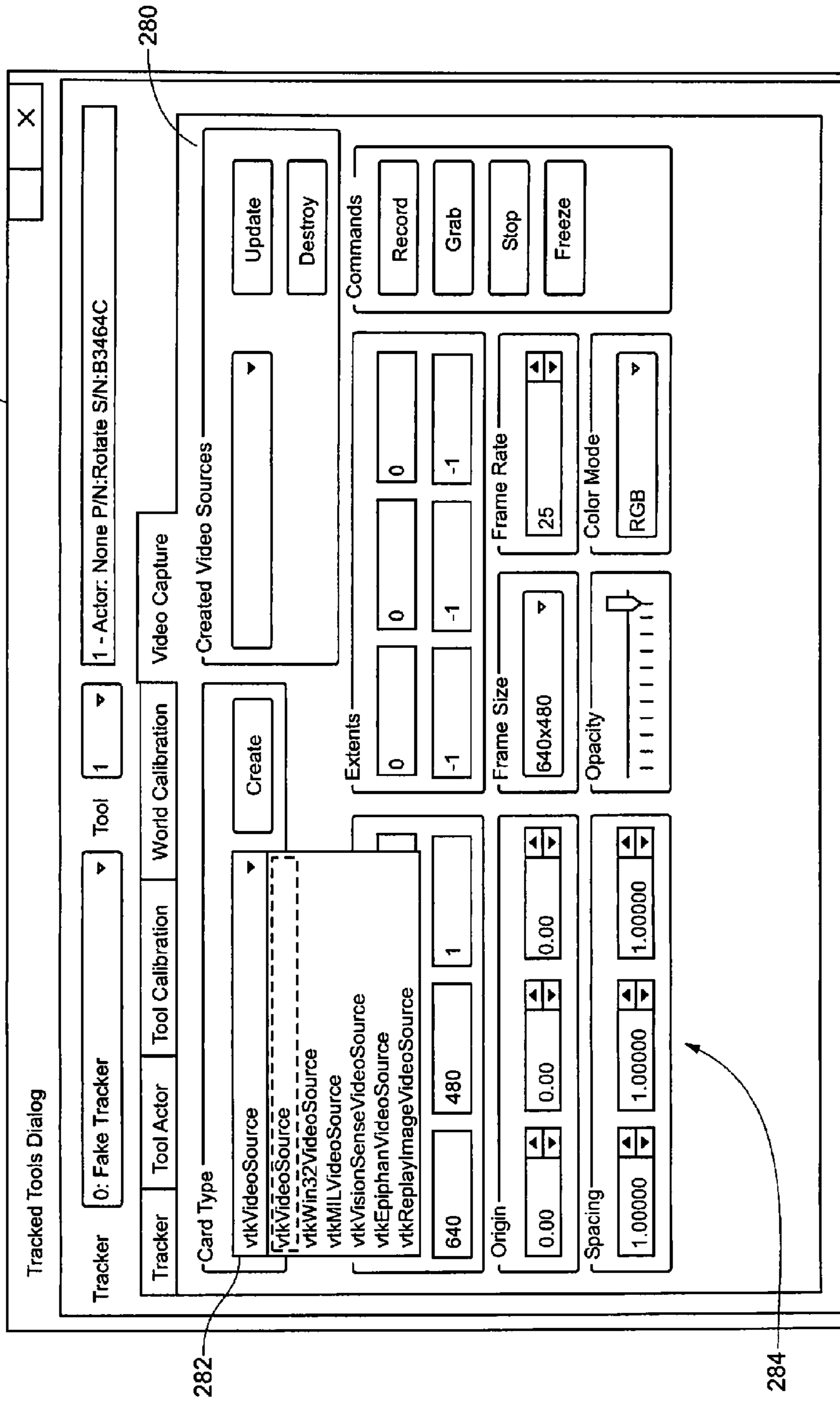
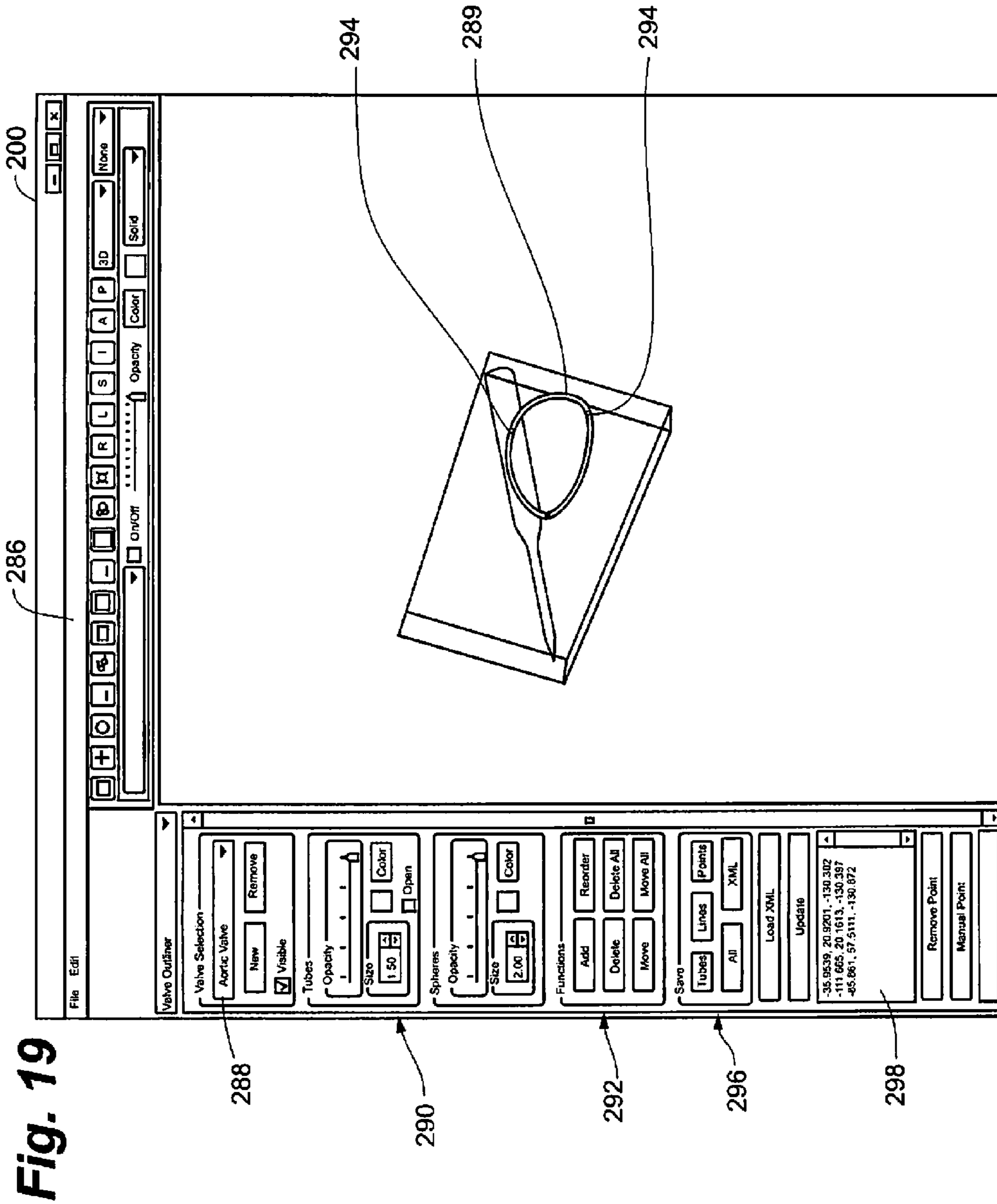


Fig. 18





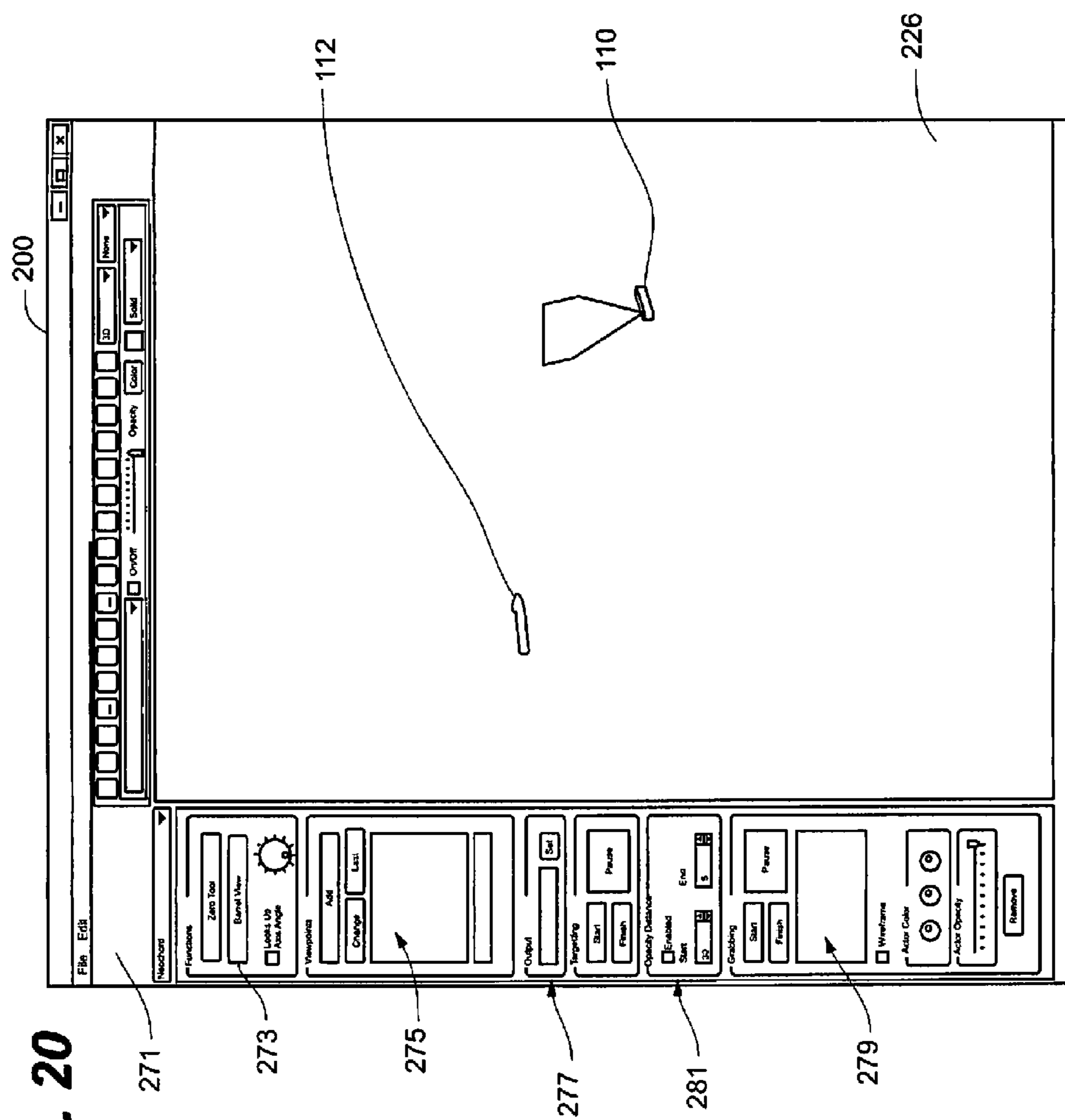
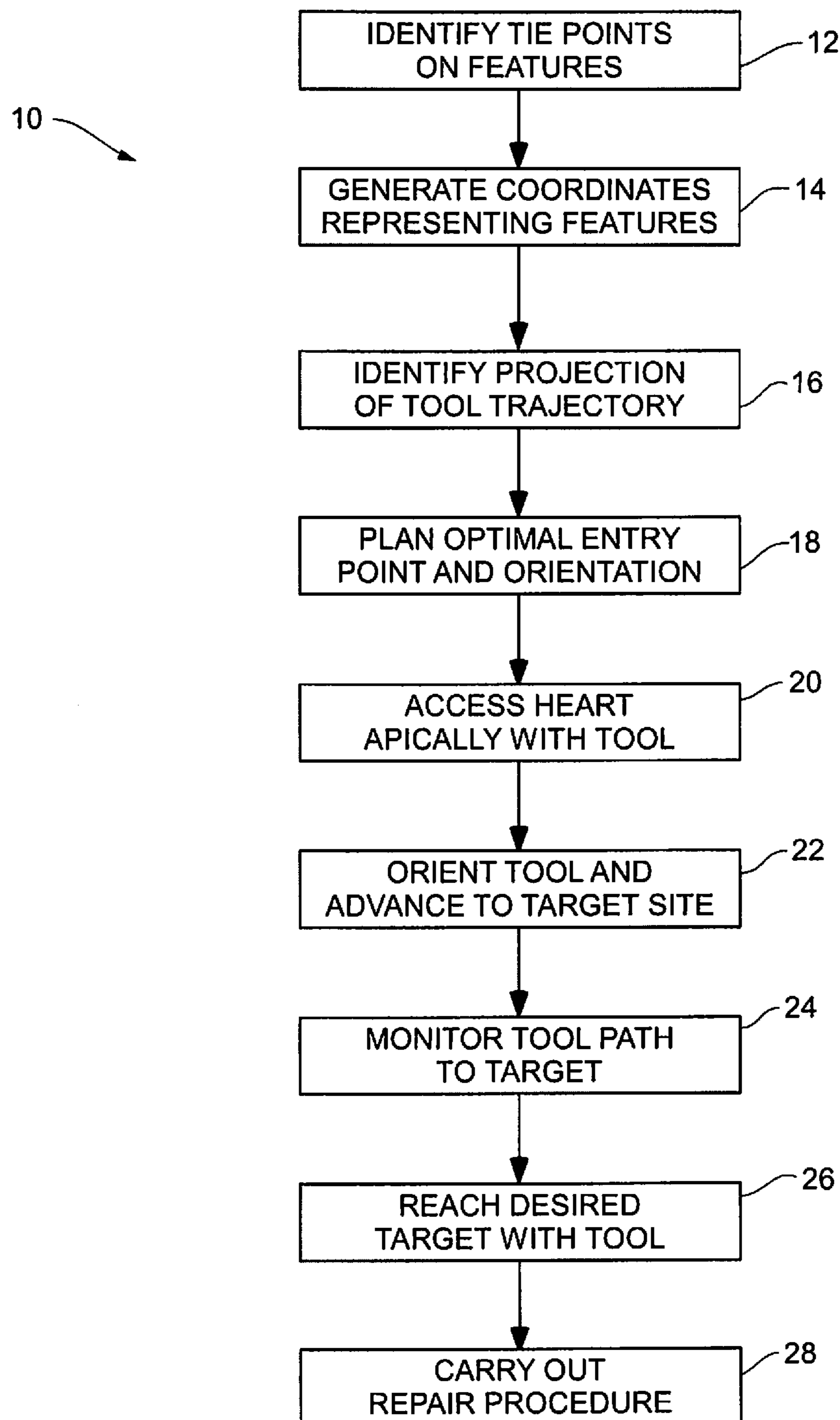


Fig. 20

Fig. 21

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SURGICAL NAVIGATION FOR REPAIR OF HEART VALVE LEAFLETS

RELATED APPLICATION

The present application claims the benefit of U.S. Provisional Application No. 61/565,795 filed Dec. 1, 2011, which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to minimally invasive repair of heart valve leaflets. More particularly, the present invention relates to surgical navigation systems for minimally invasive repair of heart valve leaflets.

BACKGROUND OF THE INVENTION

Degenerative mitral valve disease (DMVD) is a common heart valve disorder in which there is incomplete valve closing, often resulting in shortness of breath, fluid retention, heart failure and premature death. DMVD is characterized by abnormal connective tissue of the mitral valve, resulting in weakening and rupture of the chordae tendoneae (chords), the support structures of the mitral valve, preventing its natural closure. DMVD affects about 2% of the general population and severe, symptomatic DMVD is treated by surgical repair or replacement. Major advances in mitral repair surgery have improved short- and long-term outcomes of patients with this disease. Many such procedures can also benefit individuals having functional mitral valve disease.

Open heart cardiac surgery is highly invasive with a long recovery period, and not well tolerated by elderly or comorbid patients. Recent innovations in minimally invasive and robotic mitral repair techniques employ sternal sparing approaches to reduce the invasiveness of the procedure, but still require the use of cardiopulmonary bypass which has many associated complications. While the emerging field of transcatheter mitral valve repair avoids the risks of conventional surgery and potentially offers hopes of beating heart mitral valve reconstruction, concerns about residual mitral insufficiency, durability and inadequate mitral valve repair have been raised.

Devices capable of performing off-pump, mitral valve repair for certain forms of DMVD, such as those disclosed in U.S. Patent Publication Nos. 2008/0188873, 2010/0174297, 2009/0105279 and 2009/0105751, have recently been developed. Such devices can use trans-apical access to approach and capture the prolapsed portion of the mitral valve leaflet, attach a suture and anchor it at the apex, constraining the flailing leaflet and eliminating the prolapse. Currently, this procedure relies exclusively on trans-esophageal echocardiography (TEE) guidance in the form of 2D single plane, bi-plane, and 3D imaging. While TEE has thus far proven adequate for the final positioning of the tool and grasping the leaflet, there have been concerns relating to the navigation of the tool from the apex to the target MV leaflet. TEE guidance can be problematic as it may not always be possible to maintain appropriate spatial and temporal resolution in 3D, and it may not always be possible using single 2D and 2D bi-plane views to simultaneously maintain both the tool tip and target site in the field of view. Using 2D echo it also can be difficult to ensure that the tool tip, rather than a cross section of the tool shaft, is visualized. Due to these navigation challenges, the tool can become caught in the region below the valve leaflet, risking leaflet perforation.

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After extensive animal studies, the devices described in the above-referenced publications are currently undergoing preliminary in-human trials for the repair of flailing mitral valves. The procedure uses off-pump trans-apical left ventricle (LV) access. Correct leaflet capture is verified using a fiber-optic based detection mechanism. After leaflet capture has been verified, an ePTFE (expanded polytetrafluoroethylene) suture is pulled through the leaflet and the tool is retracted with both ends of the suture. The suture is fixed at the leaflet with a girth hitch knot, adjusted under Doppler echo to ensure minimum mitral regurgitation (MR) and then secured at the apex using a pledget. Multiple neochordae are typically used to ensure optimal valvular function. The single largest problem in navigating the device to the MV target region is that echo imaging must simultaneously keep the target region (MV line of coaptation) and the tool tip in view.

As noted above, traditional approaches for repairing and replacing mitral valves have relied on placing the patient on cardiopulmonary bypass (on-pump) and accessing the arrested heart directly via a median sternotomy. However, because this approach has the potential for major undesired neurological, vascular and immunological sequelae, there is a push towards performing such procedures in a minimally-invasive fashion. Preliminary experience on animals and humans has indicated that ultrasound guidance alone is often not sufficient for minimally invasive procedures. It would therefore be desirable for a system to provide enhanced surgical guidance in such minimally invasive procedures for repairing patient heart valves.

SUMMARY OF THE INVENTION

To improve the overall navigation process for minimally invasive repair of heart valve leaflets, an augmented reality technique capable of providing a robust three-dimensional context for transesophageal echocardiography data has been developed. In the context of various embodiment of the invention, augmented reality essentially refers to a system in which the primary environment is virtual but the environment is augmented by real elements. In this real-time environment, the surgeon can easily and intuitively identify the tool, surgical targets, and high risk areas, and view tool trajectories and orientations.

In one embodiment, a surgical navigation system is provided to aid in conducting a heart valve repair procedure. System can include a heart valve repair device and medical imaging system including an imaging probe to provide real-time imaging of the anatomy of the patient. A tracking system can include one or more sensors incorporated into the heart valve repair device and imaging probe to track location and orientation data of those devices in real-time three-dimensional space. A computer processor can receive the imaging data from the imaging system and the location and orientation data from the tracking system and can also create virtual geometric models of the heart valve repair system and the imaging probe. At least one display device can present the virtual geometric models overlain onto the real-time imaging data in a common coordinate system showing the models moving in real-time based on the location and orientation data from the tracking system.

In a further embodiment, a surgical navigation system for use in aiding a surgical procedure can be provided. At least one sensor can be incorporated into an imaging probe of a medical imaging system and a heart valve repair device. Real-time imaging data can be acquired by the imaging system with the imaging probe. Virtual geometric models of the imaging probe and the heart valve repair device are also

created. The virtual geometric models can then be overlain onto the imaging data in a common coordinate system. The location and orientation of the imaging probe and the heart valve repair device can subsequently be displayed in real-time three-dimensional space with tracking information obtained by the sensors.

The above summary of the various embodiments of the invention is not intended to describe each illustrated embodiment or every implementation of the invention. This summary represents a simplified overview of certain aspects of the invention to facilitate a basic understanding of the invention and is not intended to identify key or critical elements of the invention or delineate the scope of the invention.

BRIEF DESCRIPTION OF THE FIGURES

The embodiments of the present invention may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. 1 is a schematic representation of a surgical navigation system according to an embodiment of the present invention.

FIG. 2 is a perspective view of a surgical navigation system according to an embodiment of the present invention.

FIG. 3 is a partial view of a transesophageal echocardiogram probe that can be used with a surgical navigation system according to an embodiment of the present invention.

FIG. 4 is a perspective view of a heart valve repair system that can be used with a surgical navigation system according to an embodiment of the present invention.

FIG. 5A is a partial perspective view of the heart valve repair system of FIG. 4.

FIG. 5B is a partial perspective view of the heart valve repair system of FIG. 4.

FIG. 6 is a partial perspective view of a heart valve repair system for use with a surgical navigation system according to an embodiment of the present invention.

FIG. 7 is a partial perspective view of a heart valve repair system for use with a surgical navigation system according to an embodiment of the present invention.

FIG. 8 is a partial perspective view of a heart valve repair system for use with a surgical navigation system according to an embodiment of the present invention.

FIG. 9 is a partial perspective view of a heart valve repair system for use with a surgical navigation system according to an embodiment of the present invention.

FIG. 10 is a perspective view of a calibration system for a surgical navigation system according to an embodiment of the present invention.

FIG. 11 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 12 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 13 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 14 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 15 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 16 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 17 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 18 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 19 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 20 is a screenshot of a surgical navigation system according to an embodiment of the present invention.

FIG. 21 is a flowchart depicting steps of heart valve repair process according to an embodiment of the present invention.

While the present invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the present invention to the particular embodiments described. On the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present invention.

DETAILED DESCRIPTION

In the following detailed description of the present invention, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, one skilled in the art will recognize that various embodiments of the present invention may be practiced without these specific details. In other instances, well-known methods, procedures, and components have not been described in detail so as to not unnecessarily obscure aspects of the present invention.

According to an embodiment of the present invention, a visualization environment uses tracking technology to locate both a heart valve repair tool and a transesophageal echocardiogram (TEE) probe in 3D space, making it possible to represent real-time echo images with virtual geometric models of both devices and interactively defined anatomy within a common coordinate system. Exemplary repair tools can include those disclosed in U.S. Patent Publication Nos. 2008/0188873, 2010/0174297, 2009/0105279 and 2009/0105751, each of which is incorporated by reference. Sensors from, for example, the Aurora (Northern Digital, Waterloo, Canada) magnetic tracking system (MTS) can be integrated into the repair tool and onto the TEE probe of a, for example, Philips iE33 ultrasound.

Geometric models of each device can be created with appropriate computer software and the tools appropriately calibrated. One embodiment of such geometric models can be implanted using the Visualization Toolkit (<http://www.vtk.org/doc/release/5.0/html/classes.html>) using spline filters and STL file readers found in the open-source VTK software libraries, which is incorporated by reference herein. Specifically, classes such as the `vtkSTLReader` and `vtkSplineFilter` can be utilized, each of which is incorporated by reference. Axes with 10 mm markings can be projected from the virtual representation of the tool, indicating the forward trajectory of the tool and the direction of the opening jaws. The system greatly facilitates a surgeon's ability to plan the tool trajectory towards a desired target site, such as a heart valve.

In addition to representations of the tools, tracking the TEE image data makes it possible to define anatomy of interest (aortic valve annulus, target location (e.g., mitral valve line of coaptation), and regions to be avoided (e.g., mitral valve annulus) for contextual purposes. In the case of mitral valve repair, the objective is to identify the plane of the mitral valve annulus in order to be able to navigate the repair tool quickly and safely to the appropriate place within the valve annulus to proceed with the repair under. With regard to an aortic valve repair, a primary issue is identifying the critical structures associated with the valve so that a new valve can be placed in such a way that it does not block the coronary vessels fed by the coronary ostia and positioned appropriately with respect to the base of the aorta. In both types of procedures, target

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points can be indentified with ultrasound shown as three dimensional locations in space that can be fitted with lines, rigs or planes to identify the location of the coronary ostia, annuli of the valves, the line or plane defining the base of the valve or any calcifications near the aortic valve. As will be described further herein, each of these marked regions can be updated to reflect its motion during the procedure, using motion models acquired from pre-operative images, by extracting motion parameters from the intra-operative ultrasound images, or by implanting and tracking one or more magnetically or sonically traced fiducial markers secured close to or on the respective target region.

This augmented reality system is designed to assist the surgeon with three related navigation tasks of; planning the access point and trajectory; maintaining a safe and direct entry through the mitral valve commissure into the left atrium, and establishing the correct tool orientation at the line of coaptation so the repair device can grasp the flailing leaflet. As shown in FIG. 21 such a process 10 includes, prior to making the apical entry incision, the echocardiographer identifying a minimal number of tie-points along the pertinent anatomy (aortic valve annulus, mitral valve annulus, line of coaptation) at step 12. From these coordinates, at step 14 a series of coordinates are generated to represent these features in virtual space. Next, the surgeon uses a desired trajectory projection of the repair tool determined at step 16 to plan the optimal entry point and orientation at step 18. After apical access at step 20, the surgeon simply orients and points the tool trajectory towards the desired target site and advances the tool at step 22, monitoring the virtual representations as seen on the real-time echo image data at step 24. By overlaying the virtual elements on the real echo image data, the surgeon is able to assess the accuracy and reliability of the virtual representations in real time. Once at the desired target location at step 26, the procedure can return to the standard workflow for carrying out the repair procedure at step 28, since additional guidance is no longer needed. In addition, any relevant structure that can be identified within or surrounding the heart in ultrasound, with a tracked electrophysiological device or which can be identified in preoperative image and registered into the ultrasound coordinate frame can be similarly incorporated into the system.

One embodiment of a surgical navigation system 100 as described above is depicted in FIGS. 1 and 2. The primary components of the system include a magnetic tracking system 102, an ultrasound imaging system 104 and a computer 106 with one or more output monitors 108. A TEE probe 110 of the ultrasound imaging system 104 can be integrated with the magnetic tracking system 102. A heart valve repair device 112 can also interface with the magnetic tracking system 102.

The magnetic tracking system 102 can utilize sensors interfacing with each of the TEE probe 110 and the heart valve repair device 112 to track the location and orientation of those tools with respect to the magnetic field generator 117 of the system 102, which can be placed on the operating room table underneath the patient. This information can be used to place both the TEE probe 110 and the heart valve repair device 112 into a common virtual environment. Each of the sensors can communicate with the magnetic sensor control unit 116 that is linked to each sensor by a sensor interface unit 118. In one embodiment, the system 102 uses the Northern Digital Aurora magnetic tracking system. In such an embodiment, the magnetic tracking system 102 is controlled using NDI API software 113 and interfaces with the navigation application suite 111 on the computer 106 with AIGS API software 114. The system can utilize three tracked sensors, one mounted to the TEE probe 110 and two mounted to the heart

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valve repair device. In other embodiments, greater or fewer sensors can be used with each device. Although described as using a magnetic tracking system 102 to track the ultrasound probe and surgical tools, it should be understood that various other tracking systems could be utilized in accordance with the present invention. For example, other types of tracking that could be used include acoustic, radio-frequency, fiber optic, image based and x-ray.

Referring now to FIG. 3, there can be seen a TEE probe 110 that can be used with embodiments of the present invention. The TEE probe 110 includes an ultrasound transducer that interacts with the ultrasound system 104 to provide echo images, as is known in the art. In the present invention, at least one sensor 130 is mounted to the TEE probe 110. Sensor 130 can be a six degree of freedom, magnetically tracked sensor. In one embodiment, as shown in FIG. 3, the sensor 130 is mounted on a side surface of the probe 110. In other embodiments, the sensor 130 can be mounted on an upper or lower surface of the probe or integrated inside the probe casing. Sensor 130 can be mounted to probe 110 with an adhesive, such as, for example a Loctite 3554 UV cured adhesive. Sensor 130 can be permanently or removably mounted to probe 110. In one embodiment, sensor 130 can be a single use, disposable sensor that can be utilized due to potential sensor damage and cleaning/sterilization issues that can arise with long term use. Sensor 130 can also be integrated into a removably mountable cap that can be mounted to the probe 110 during a procedure and then removed for cleaning prior to a subsequent procedure.

FIGS. 4-9 depict a heart valve repair device 112 that can be used with embodiments of the present invention. Device 112 generally includes a handle assembly 140 and a capture assembly 142 with an elongate shaft 144 extending therebetween. An actuator 146 is located at a proximal end of the device 112 for operating capture assembly 142. As can be seen in FIGS. 5A and 5B, capture assembly 142 can include a first clamping jaw 148 and a second clamping jaw 150. Clamping jaws 148, 150 are slidably disposably relative to each other with actuator and can be used to capture tissue, such as a heart valve leaflet, therebetween. Once tissue is captured between clamping jaws 148, 150 a needle 152 can penetrate the tissue to insert a suture 154 into the tissue. Further details of heart valve repair devices useable with the present invention are disclosed in U.S. Patent Publication No. 20090105751, which is incorporated by reference herein. Although one specific heart valve repair device is shown, it should be understood that the present invention can be adapted for use with any type of heart valve repair device.

Repair device 112 as used with the present invention can incorporate two sensors in addition to the sensor 130 utilized with the TEE probe 112. In one embodiment, a first sensor 156 can be disposed with a rubber cylinder positioned within a groove 158 in the shaft 144 of the device near the handle assembly 140. This sensor can be a five degree of freedom magnetic sensor that is used to track the opening and closing of the capture assembly 142 clamping jaws 148, 150. A second sensor 160 can also be disposed in a groove 162 in the shaft 144. The second sensor 160 can be a six degree of freedom magnetic sensor that is used to track the movement of the repair device 112 itself. In one embodiment, the second sensor 160 can be held in the groove by an adhesive. Each sensor 156, 160 includes corresponding wires 164, 166 through which the positional data is transmitted that are routed out of the tool 112 and back to the sensor interfaces 118 and sensor control unit 116. In one embodiment, the wires 164 for the first sensor are fixed to the shaft 144 at location 164a and again adjacent the exit point of wires 164

from device at location **164b**, with a length of slack **164c** that allows the sensor to move along the shaft **144** when actuator **146** is employed to move the clamping jaws **148, 150**. Wires **166** for second sensor **160** can be adhered to the shaft **144** until the wires **166** exit the device **112**. Wires **164, 166** can exit through an opening **168** in the body of the repair tool **112**. In one embodiment, opening includes a grommet through which the wires **164, 166** extend.

One or both of the heart valve repair device **112** and the TEE probe **110** can be calibrated for use with the system **100**. In this context, calibration refers to the process of defining the coordinate frame of a device relative to the magnetic tracking sensors or other sensors used to track the device. Heart valve repair device **112** can be calibrated with a calibration jig **170** such as shown in FIG. **10**. The jig **170** is configured such that the tip of the repair device **112** is always in the same location when held in the jig **170**. In one embodiment, the jig **170** can comprise two milled acrylic blocks. A reference sensor **172** is positioned near the tip of the repair device **112** and can be rigidly mounted to the jig **170**. In one embodiment, the sensor can be an NDI Aurora sensor. The jig **170** can also include a series of divots **174** milled into the jig **170** near the tip of the repair device **112**. In one embodiment, eight spherical divots are milled in a non-symmetrical pattern. A geometric model of the jig **170** can be created from a micro-CT of the jig, with the origin of the model defined at the repair device **112** tip and the z-axis extending along the long axis of the repair device **112**. Using the micro-CT data, the locations of the milled divots are then defined for the model. Then, a magnetically tracked tool **176** is used to calibrate the repair device **112** by interfacing the tool **176** with each of the divots **174**. In one embodiment, a tip **178** of the tool **176** can be shaped to fit within the divots **174**. In one embodiment, the device **112** can be provided to an end user having been pre-calibrated for use during production.

The TEE probe **110** can be calibrated by using a magnetically tracked tool intersecting the ultrasound image plane. In one embodiment, the magnetically tracked tool can be a previously calibrated repair device **112**. In one embodiment, the computer **106** can monitor the accuracy of the calibration during a surgical procedure and warn the users of potential inaccuracies in the model. In such an embodiment, the system could also intra-operatively correct calibration errors during the procedure.

The ultrasound image data acquired by the TEE probe **110** is transmitted from the ultrasound system **104** to the computer **106** for integration into the virtual scene created with the system **100**. The data can be transferred from the ultrasound system **104** to the computer with a converter **120**. In one embodiment, the converter is the Epiphan DVI2USB converter. In such an embodiment, the converter **120** can be managed by the Epiphan Application Program Interface **121**.

The computer **106** operates to integrate image data from the ultrasound system **104** with tracking information from the magnetic tracking system **102** to present virtual representations of the heart valve repair tool **112** and TEE probe **110** in a common 3D environment. Using the tracked TEE image data, geometric models of pertinent anatomy, such as mitral and aortic valve annuli, are added to provide the surgeon with a significantly more intuitive environment for performing the surgical procedure, as will be described in more detail below.

In one embodiment, two monitors **108** are used to provide a split screen view of the system. In such an embodiment, one monitor can be used for viewing by the surgeon and the other can be used by the echocardiographer and technician. In other embodiments, only one monitor can be used or more than two monitors can be used.

The computer **106** can operate a software platform that provides an augmented reality viewpoint for a surgeon performing a procedure, such as repair of a heart valve. The software platform provides the system for integrating the real-time information from the magnetic tracking system **102** with the real-time information from the ultrasound system **104, 110**. The information is displayed on a user interface **200** on the one or more computer monitors **108** showing the ultrasound image data with dynamic virtual geometric representations of surgical tools **202** and anatomy **204** as will be discussed in more detail with regard to FIGS. **11-20**.

To establish the user interface, the software platform must render the various components for display on the interface. The body or shaft **144** of the heart valve repair device **112** can be rendered on the system as a solid shape derived from CAD drawings of the device. Either a portion of the length of the body of the device (e.g., 2 cm or 4 cm) or the full body can be rendered. The tip or capture assembly **142** can also be generated from CAD drawings using the same calibration matrix as the body. The location where the needle **152** used by the device to penetrate tissue exits from the shaft **144** can be marked with a sphere **206**. The sphere can define two axes, a first axis **208** can be aligned with the direction of the tool trajectory and a second axis **210** can be orthogonal to the first axis **208**. Repair device **112** can be displayed either as opaque or transparent object. In one embodiment, the device **112** automatically fades to transparency as it approaches target tissue, with distances at which this occurs selectable by the user. In such an embodiment, the sphere marker **206** showing the location of the needle can remain opaque at all times.

FIG. **13** depicts an opening screen **220** of the user interface **200** according to an embodiment of the present invention. Opening screen **220** can include a general functions render pane **222** that allows rendering of an object to be manipulated and a module render pane **224** for displaying specific operations that can be undertaken in a given module. The scene render pane **226** will display the navigation data for a given procedure. A drop down menu **228** can be used to access the user interfaces for various modules.

A tracked tool module **230** is displayed in FIG. **14**. A tracked tools dialog window **232** shown in FIGS. **15-18** can be opened by selecting the corresponding button **233** on the tracked tool module **230**. A tracker pull down menu **234** can be used to select a specific tracked tool. Once a tool is selected, tracker control buttons **236** can be used to control tracking of the tool. The opacity of all tools can be controlled with the global tool opacity slider **238**. Opacity of a specific tool can also be adjusted on the tracked tool module **230** by selecting from the tool pull down bar **240** and using the corresponding slider **242**. Display of the selected tool in wireframe and display of the tool axes can also be turned off and on with corresponding check boxes **244, 246** on the tracked tool module **230**.

FIGS. **15-18** display various aspects of the tracked tools dialog window **232**, which can provide the basic functionality of the tracked tool module **230** as well as additional functionality. A tracker pane **248** of the window **232** is shown in FIG. **15**, and includes a tracker pull down menu **234** and tracker control buttons **235**. A tool pull down menu **240** allows selection of a specific tool. A new tracking system box **251** allows a new system to be added with an initialize tracker button **250** to actuate the new system. A specific configuration for a tracking can be loaded or saved with buttons in the configuration box **252**.

A tool actor pane **252** of the tracked tools dialog window **232** is shown in FIG. **16**. The tool actor pane **252** allows all virtual actors to be interactively modified in real time. The

tool actor can be selected from a tool actor dropdown **254** and a new tool can be rendered with the add tool button **256** after an acting tool is selected. Various information on the tool can be provided and modified in the information box **258**. Callbacks for the tool are contained in a callbacks box **260**. Video sources for use with the tracked tool can be added, removed and viewed in the video sources box **262**.

The tool calibration matrix **266** is displayed on a tool calibration pane **264** of the dialog box **232** as shown in FIG. **17**. The matrix can be manually entered into the boxes or can be copied and pasted into a text box **268**. Various matrix controls **270** for manipulating the data are also provided. A tip calibration box **272** can allow calibration of a tool tip and can also display the root mean squared error of the calibration **274**. The orientation and tip location of a tool can also be obtained from a previously saved tool with the orientation box **276**. A command box **278** can alternatively be used to manually calibrate the rotation and translation controls. The tracked tools dialog window **232** can also include a video capture pane **280** as shown in FIG. **18**. This pane can provide for selection of a specific source video card from a pull down menu **282** and display information **284** about the source.

An anatomical feature module **286** is shown in FIG. **19**. A drop down menu **288** and associated controls allow a specific anatomical feature to be selected, added or removed, such as for example, the mitral valve or the aortic valve. Various controls **290** can be used to adjust the rendering of the anatomical feature **289**. A plurality of function keys **292** is also provided. Keys **292** can be used to manage tie points **294**, which can be denoted by small spheres on the interface **200**. Tie points **294** can be one or more 3-dimensional points representing a tracked location on an anatomical landmark such as the annulus of the mitral valve or aortic valve or other structure as described earlier. The tie points can be used to create a model of the structure with a suitable curve. Tie points can also be displayed to represent specific points on the structure, such as a desired grasping point along a valve leaflet. The save/load data buttons **296** allow tie points to be saved into the system or loaded from memory. A manage data menu **298** allows the tie point data to be edited and removed. In an alternative embodiment, tie points can be selected and defined on the ultrasound device **104**, rather than on the computer **106**.

In one embodiment, anatomical structures can be tracked as they move, either by using image-based tracking or by introducing tracked sensors close or attached to the anatomical structures. The tracking information can be used to dynamically update the virtual representations of the anatomy created with the tie points. An advantage of updating the target regions dynamically during the procedure is that in the case of mitral valve repair, the repairing instrument is less likely to be inadvertently guided into an inappropriate structure, causing potential damage. In the case of the aortic valve, the advantage of dynamically moving the target structures is that the procedure can be carried out without temporarily stopping the heart or inducing rapid pacing, both of which would stop the target motion, but would add additional risk to the patient.

A repair device module **271** is shown in FIG. **20**. The scene render pane **226** displays the tracked repair tool **112** and TEE probe **110**. Functions buttons **273** can be used to control various aspects of the devices. Various viewpoints from which the user can view the procedure can be selected and modified with viewpoints controls **275**. The scene render pane **226** can display viewpoints in various ways, including a single view, a split, two pane view and a four pane view. The viewpoint of the virtual camera for a specific view can be

controlled with the computer mouse, which can rotate, pan, zoom, etc. the view, to allow the user to define a specific view. One view that can be utilized is a barrel view, which sets the camera a set distance, such as 10 cm, above the repair tool **112** aligned along the main axis of the tool **112**. Barrel view can be activated with a corresponding function button **273**. In an alternative embodiment, rather than the user defining and controlling the viewing angles for the augmented virtual reality scene, the viewing angles can be automated for a specific type of procedure. Views can also be based on pre-operatively acquired data. In an alternative embodiment, the images can be displayed stereoscopically to the observer. Navigation output controls **277** provide tracking and control of data relating to navigation of the repair device **112** to the target tissue structure and grasping controls **279** provide tracking and control of data relating the grasping function of the repair tool **112** clamping jaws **148**, **150**. These tracking functions can be activated manually, or can be performed automatically and can provide for recording, storage and later playback. Automatic opacity of the tool at specific distances from the target site can be controlled with opacity controls **281**.

It has been found that a surgical navigation system such as system **100** can significantly reduce the surgical time needed to perform a minimally invasive procedure, such as repair of a heart valve leaflet. In one study, the mean task completion time fell by a factor of almost six when using such a system. Such a system also leads to more direct navigation paths to the target tissue, which results in a safer procedure. For example, in repair of a heart valve leaflet, a repair device can inadvertently enter an area dangerous to a patient, such as the left ventricular outflow tract or cause damage to the leaflet itself when the path to the tool is not guided as described herein.

Although described herein as providing surgical navigation for capturing heart valve leaflets, embodiments of the present invention can also be applied to targeting any intracardiac structure for repair or replacement, such as full valve replacement or other structural heart repair. Sutures and other repair devices can be delivered via the disclosed system for repair purposes.

In a further embodiment, a surgical navigation system as described herein can be utilized as a training system. Thus, in lieu of utilizing the system to aid in guiding an actual surgical procedure, the system can be utilized to train surgeons, echocardiographers and others for performing heart repair procedures.

Various embodiments of systems, devices and methods have been described herein. These embodiments are given only by way of example and are not intended to limit the scope of the present invention. It should be appreciated, moreover, that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Moreover, while various materials, dimensions, shapes, implantation locations, etc. have been described for use with disclosed embodiments, others besides those disclosed may be utilized without exceeding the scope of the invention.

The invention claimed is:

1. A surgical navigation system, comprising:

- a heart valve repair device;
- a medical imaging system, the medical imaging system including an imaging probe that is movable relative to a patient to provide real-time imaging data of anatomy of the patient;
- a tracking system adapted to track location and orientation data of the heart valve repair device and the imaging probe in real-time three-dimensional space, the tracking system including a plurality of sensors that provide the

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location and orientation data, with at least one sensor incorporated into the heart valve repair device and at least one sensor incorporated into the imaging probe; a computer processor adapted to receive the imaging data from the medical imaging system and the location and orientation data from the tracking system, the processor further adapted to create virtual geometric models of the heart valve repair device and the imaging probe; at least one display device, the display device operably connected to the computer processor and adapted to present the virtual geometric models of the heart valve repair device and the imaging probe overlain onto the real-time imaging data in a common coordinate system, the virtual geometric models moving in real-time according to the location and orientation data.

2. The surgical navigation system of claim 1, wherein the computer processor is further adapted to create virtual geometric models of one or more anatomical features of the patient based on the imaging data and the display device is adapted to present the geometric models of the one or more anatomical features along with the virtual geometric models of the imaging probe and heart valve repair device in the common coordinate system.

3. The surgical navigation system of claim 2, wherein a location and orientation of one or more of the virtual geometric models are automatically dynamically updated based on movement of the corresponding anatomical features.

4. The surgical navigation system of claim 1, wherein the tracking system is a magnetic tracking system including a magnetic field generator, and the sensors are magnetically tracked relative to the field generator.

5. The surgical navigation system of claim 1, wherein the imaging system is an ultrasound imaging system and the imaging probe is a transesophageal echocardiography probe.

6. The surgical navigation system of claim 1, wherein one sensor is incorporated into the imaging probe and two sensors are incorporated into the heart valve repair device.

7. The surgical navigation system of claim 6, wherein a first sensor tracks a body portion of the heart valve repair device and a second sensor tracks an actuation portion of the heart valve repair device.

8. The surgical navigation system of claim 1, wherein the heart valve repair device includes an elongate shaft and a tip, the tip including movable clamping jaws.

9. The surgical navigation system of claim 8, wherein a first sensor tracks a location and orientation of the elongate shaft of the heart valve repair device and a second sensor tracks movement of the clamping jaws.

10. The surgical navigation system of claim 1, further comprising a calibration jig and a calibration tool that is tracked by the tracking system, the calibration jig adapted to hold the heart valve repair device as the calibration tool is used to define a coordinate frame of reference of the heart valve repair device relative to the at least one sensor incorporated into the heart valve repair device.

11. A method of providing a surgical navigation system, comprising:

- incorporating at least one sensor into an imaging probe of a medical imaging system;
- incorporating at least one sensor into a heart valve repair device;
- obtaining real-time imaging data of anatomy of a patient with the imaging probe;
- using a computer processor to automatically create virtual geometric models of the imaging probe and the heart valve repair device;

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using a computer processor to automatically overlay the virtual geometric models of the imaging probe and the heart valve repair device onto the imaging data in a common coordinate system on a display; and

using a computer processor to automatically represent a location and orientation of each of the imaging probe and the heart valve repair device in real-time three-dimensional space on the display with tracking information obtained by the sensors.

12. The method of claim 11, further comprising creating virtual geometric models of one or more anatomical features of the patient based on the imaging data and displaying the virtual geometric models of the one or more anatomical features in the common coordinate system on the display.

13. The method of claim 12, wherein creating virtual geometric models of one or more anatomical features includes tracking movement of one or more of the anatomical features, and wherein a location and orientation of one or more of the virtual geometric models are automatically dynamically updated based on the tracked movement.

14. The method of claim 11, wherein the sensors are magnetically tracked sensors.

15. The method of claim 11, wherein obtaining the real-time imaging data includes obtaining the imaging data with an ultrasound system.

16. The method of claim 11, further comprising calibrating the heart valve repair device to define a coordinate frame of reference of the heart valve repair device relative to the at least one sensor of the heart valve repair device.

17. The method of claim 11, further comprising calibrating the imaging probe to define a coordinate frame of reference of the imaging probe relative to the at least one sensor of the imaging probe.

18. A surgical navigation system, comprising:
means for repairing a heart valve of a patient;
means for providing real-time imaging data of anatomy of the patient;

means for tracking location and orientation data of the means for repairing a heart valve and the means for providing real-time imaging data in real-time three-dimensional space, the means for tracking including at least one means for sensing location and orientation incorporated into the means for repairing a heart valve and at least one means for sensing location and orientation incorporated into the means for providing real-time imaging data;

means for creating virtual geometric models of the means for repairing a heart valve and means for providing real-time imaging data and overlaying the geometric models onto the real-time imaging data in a common three-dimensional coordinate system;

means for displaying the virtual geometric models overlain onto the real-time imaging data showing the location and orientation data in real-time.

19. The surgical navigation system of claim 18, wherein the means for tracking includes means for generating a magnetic field for tracking the means for sensing.

20. The surgical navigation system of claim 18, wherein the means for providing real-time imaging data provides ultrasound imaging data.

21. The surgical navigation system of claim 18, wherein the means for repairing a heart valve includes a body portion and a means for grasping, and a first means for sensing tracks location and orientation of the body portion and a second means for sensing tracks operation of the means for grasping.

22. The surgical navigation system of claim 18, further comprising a means for calibration of the means for repairing a heart valve.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,938,283 B2
APPLICATION NO. : 13/692027
DATED : January 20, 2015
INVENTOR(S) : Zentgraf et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At Column 5, Line 1, please delete “points can be indentified with ultrasound shown as three” and insert in its place --points can be identified with ultrasound shown as three--.

Signed and Sealed this
First Day of August, 2017



Joseph Matal
*Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office*